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REF: SHA/23371

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**APPEAL AGAINST LONDON REGION AREA TEAM, NHS COMMISSIONING BOARD "NHS ENGLAND" DECISION TO REFUSE AN APPLICATION BY MOJJI LS LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 381 CHURCH LANE, KINGSBURY, LONDON, NW9 8JB UNDER REGULATION 25**

**1 Outcome**

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

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## 1 The Application

By application dated 10 November 2019, Mojji Ls Ltd ("the Applicant") applied to NHS Commissioning Board ("NHS England") for inclusion in the pharmaceutical list at 381 Church Lane, Kingsbury, London NW9 8JB 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 None.

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

1.2 As the Applicant is an online based pharmacy, they are based in an office on a road that is not busy with pedestrians. The building is locked with no entry to any members of the public and anyone wanting access has to ring the bell and only after knowing they are permitted then will be let in e.g. staff members and delivery drivers.

1.3 Secondly, the Applicant will make it very clear to all their patients they are a delivery only pharmacy meaning they are not allowed to come and collect their prescriptions from them and if they intend to do that then the Applicant will let them know that the services are not suitable for them and they will be signposted to the closest retail pharmacy that is not a distance selling pharmacy. This will be reinforced in the sign-up forms where the Applicant will clearly state in the form that they are an online pharmacy only and they DO NOT allow for face to face contact on the premises or within the vicinity of the premises and if they have any queries they must contact either by phone, email or via the website.

1.4 Furthermore, as the Applicant is an online pharmacy, they will be providing their services nationwide and not locally and so do not intend on competing in the local market.

1.5 Therefore, the Applicant will not pose a threat to existing pharmacies who provide an excellent service and will focus on providing a unique pharmacy service to the growing number of people who do not have time to go to pharmacies due to a busy life schedule and these people are increasing in number.

1.6 All the above information is outlined in the SOPs (attached) and advised to all patients.

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

- 1.7 There are no providers of primary medical services in the same site or in the same building therefore this point is not applicable.

Further Information in Relation to Provision of Essential Services in Accordance With the Regulatory Requirements for Distance Selling Pharmacies

- 1.8 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.
- 1.9 The Applicant's procedures ensure that they do not negatively affect local retail pharmacy businesses and they actually work together to provide the best possible NHS pharmaceutical service. The Applicant's unique service tailors for the new busier lifestyle due to work or for the elderly who are unable to leave their homes or anyone anywhere in the country that wishes to use a distance selling pharmacy service for convenience.
- 1.10 The Applicant has full comprehensive SOPs. Although the SOPs are part of their intellectual property they have made available the relevant SOPs that describe how all essential services will be provided throughout the UK whilst ensuring no face to face contact at the premises or within the vicinity of the premises.
- 1.11 Delivery of ambient medication will be provided by the Applicant's drivers, UPS or FedEx and all temperature sensitive medication will be delivered via igloo logistics in their temperature-controlled vehicles. All deliveries will be signed for so the Applicant has a trace and proof of postage and delivery.
- 1.12 There will be a registered pharmacist on-site throughout the opening hours to ensure an uninterrupted service. There will be no public access to the site. All essential services will be available throughout the United Kingdom so no discrimination for those wanting the service no matter where they live. Details are described in the Applicant's SOPs.
- 1.13 Public health services, signposting and support for self-care will be provided through the website, telephone systems and via material delivered through the post/delivery drivers, as described in the SOPs.
- 1.14 The unique business model does not pose a threat to any local retail pharmacies businesses and in fact the Applicant will sign-post local patients who want face to face contact to them, the Applicant will work with them to provide the excellent NHS services all pharmacies already provide as opposed to compete with them. The Applicant will focus on making the care of patients their primary concern and meeting their needs.
- 1.15 The Applicants robust working practices and operating procedures ensure 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 their staff.
- 1.16 In the unlikely event that a patient tries to access the essential service by coming to the pharmacy then will be turned away very politely and it will be explained to them that the Applicant cannot provide essential services to any members of the public and that is in their contract with the NHS. They will be sign posted to the nearest local pharmacy who can fulfil their immediate needs. The Applicant will remind them that it is on the website and on the consent forms they signed to get their services in the first place. All

staff are trained according to the Applicant's SOPs and they will always abide by these SOPs and they will pass this information on to the patient. The patient will be reminded that face-to-face contact is prohibited and that the Applicant only deliver via special couriers or their own drivers.

- 1.17 No advanced services will be provided on site to eliminate completely any risk of breaching the contract, as it will not be easy to explain to a patient coming in for any advanced service that they cannot take their medications with them. This is the safest option to avoid breaching the contract and at the same time not upsetting patients.
- 1.18 Please note the front door will be locked at all times with an intercom system for deliveries. The Applicant will have a private and secure internet connection and phone to enable it to connect to their customers.
- 1.19 Please see all SOPs at the end of this application.

## 2 The Decision

NHS England considered and decided to refuse the application. The decision letter dated 1 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 the London Region PSRC March 2020 meeting report.

- 2.2 The PSRC have determined that there is enough information to deal with this application without holding an oral hearing.
- 2.3 The comments received from parties is available to the PSRC panel to review.
- 2.4 The four parties that commented on the application reminded the Area team to ensure that the Applicant complied with the regulations and not to automatically approve the application.
- 2.5 In addition, Lloyds highlighted that there was no explanation of what a "non-local" delivery was.
- 2.6 Boots did not believe that there was sufficient information to make a determination.

### NHS England Considerations

- 2.7 NHS England has reviewed the application and any accompanying SOPs and additional information provided by the Applicant. NHS England needs to assure itself that the applicant [sic] and provide all the essential services in a non-face to face format and will consider if all elements of the essential services have been covered.
- 2.8 After review of the information, NHS England has identified some areas within the information provided that are either insufficient or no details have been provided. A summary is provided below.
- 2.9 With regard to Regulation 31

*(Refusal: same or adjacent premises) and to the provisions of Schedule 2 to the Regulations:*

*"Applications seeking the listing of premises that are already, or are in close proximity to, listed chemist premises.*

- 2.10 The proposed pharmacy is not on the same site or adjacent to any other pharmacy, therefore this regulation is not engaged.
- 2.11 Distance Selling premises applications
- Regulation 25 (1) Section 129(2A) of the 2006 Act(c) (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 also 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*
- 2.12 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*
- 2.13 The Applicant provided information via their application, the SOPs attached to the application and subsequent additional information.
- 2.14 It may be concluded that 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."*
- 2.15 The Applicant provided information via their application, the SOPs attached to the application and subsequent additional information.
- 2.16 The Applicant has provided no information regarding paragraph 5(2)(3) of schedule 4 of the regulations.
- 2.17 The Applicant has not explained how it proposes safely and effectively to receive requests from prescribers for urgent supplies of drugs and appliances without a prescription.
- 2.18 The Applicant has provided no information regarding paragraph 7(3) of schedule 4 of the regulations.
- 2.19 The Applicant has provided limited information regarding paragraph 8(15) of schedule 4 of the regulations.

- 2.20 The Applicant has provided no information regarding paragraph 10(1) of schedule 4 of the regulations.
- 2.21 It may be concluded that the Applicant is likely to not satisfy the criteria as set out in the Terms of Service of Pharmacists for the safe and effective provision of all essential services without face to face contact.
- 2.22 Therefore, the PSRC have determined that it is not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

#### Decision

- 2.23 Regulation 31
- 2.23.1 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.
- 2.24 Regulation 25(2)(1)(a)
- 2.24.1 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.
- 2.25 Regulation 25(2)(1)(b)(i)
- 2.25.1 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.
- 2.26 Regulation 25(2)(1)(b)(ii)
- 2.26.1 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.
- 2.26.2 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 refused.
- 2.27 Conditions of approval for a Distance Selling Pharmacy – not used as this application has been refused.

### 3 The Appeal

In a letter dated 28 May 2020 the Applicant appealed against NHS England's decision. The grounds of appeal are:

- 3.1 The Applicant honestly thought they had provided all the information needed especially since they have been working in an online pharmacy for over 6 years without once breaching the NHS contract but nevertheless [NHS England] picked up on good points which are justified and will now answer them and attached more evidence.

- 3.2 The Applicant is hoping this letter of appeal will sway [NHS Resolution's] decision especially in this time of need the country is going through and the need for small independent online pharmacies being very needed to help protect the vulnerable in our society. This pandemic will make a lot of people fear for years to come and has increased the demand for deliveries and so online pharmacies are needed now more than ever. Most of the brick and mortar pharmacies do not have the infrastructure and manpower to offer online services because they just simply do not have the time.
- 3.3 Furthermore the likes of Boots, Lloyds, Wells and Morrisons are now refusing to dossette boxes which is a much needed service and by eliminating smaller firms likes the Applicant's then the public will suffer, especially the elderly and the vulnerable who are easily confused (they are also charging for deliveries and off course if this application was granted a license it would be a FREE NHS service). Please note the Applicant has no intention of operating locally because the area they are in is saturated and so that is why they applied for a distance selling pharmacy, so they can aim to operate nationally. The only reason why the Applicant wanted to open in this location is because it is very local to where they live and they believe if they can save 3 hours of travel per day (which they currently travel to and from work) and put this effort into the pharmacy then they can make it succeed nationally.
- 3.4 The Applicant completely understands that as an organisation although online pharmacies are exempt that [you] still need to control the amount of granted applications so to prevent the market from over saturation. The Applicant knows this is probably irrelevant but they have spent over £40k on their premises to ensure that they meet all the regulations, like installed air conditioners to ensure there are no temperature excursions which till this day most pharmacies do not have. They have installed an intercom system at the front of the premises to prevent the public from walking in and just over all fully refurbished the entire place in anticipation of a license. The premises are fully online compliant, alarmed and protected.
- 3.5 The Applicant wants to bring to [NHS Resolution's] attention the fact that another 18 interested parties were notified of the application and not even one of them felt threatened enough to make representations because they are confident patients will not leave them whilst the likes of Boots and Lloyds have a knee jerk reaction to any new applications and they know that the Applicant could potentially affect their business nationally like Pharamcy2u. However, as a pharmacist the Applicant believes in fair competition and acting in the interest of patients and the public at large. Pharmacies should all work together to improve patient care and this is what they aim to do (the Applicant has friends from university who work for Boots and Lloyds and independents and does not want them to lose their jobs, the Applicant just simply wants to have an online pharmacy business and hopefully be an asset to the NHS and to the patients who use the service), the Applicant will work with pharmacies as opposed to compete. The Applicant will not refuse any prescriptions that come their way, no matter where the patients live.
- 3.6 Please note the Applicant has also signed up with hubnet which is a pharmacy quality management system which works with GPhC and the CQC registered businesses to build novel healthcare services that comply with national best practice and legislation and if they are ever in doubt they will seek advice and hope this also helps sway [your] decision in the right direction.
- 3.7 Please note the Applicant's understanding is they provide only the SOPs that are now required to prove that they are abiding by the full NHS requirements which will be attached to this appeal and all the other SOPS the Applicant has submitted to the NHS initially they have not submitted again because the assumption is [NHS Resolution] has a copy of these already and [NHS Resolution] is satisfied with them, but please do let the Applicant know if [NHS Resolution] does want all the SOPS initially submitted and they will send to [NHS Resolution]. [Note: Copy of SOP's subsequently sent to NHS Resolution].

- 3.8 Lastly to answer Lloyds when they said that the Applicant has not explained what a non-local delivery is. A non-local delivery is delivering nationwide to any patient in the UK that opts in to receive the service.
- 3.9 Now to answer [NHS England's] concerns please see below
- 3.9.1 No bullet point = NHS England's concern
- 3.9.2 Italics = The legislation
- 3.9.3 Black = the Applicant's answers

The Applicant has provided no information regarding paragraph 5(2)(3) of schedule 4 of the regulations.

*Dispensing of drugs and appliances*

(2) *Subject to the following provisions of this Part, where—*

(a) *any person presents to an NHS Pharmacist (P) a non-electronic prescription form which contains—*

*(i) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber,*

*(ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations(1) (drugs, medicines and other substances that may be ordered only in certain circumstances), signed by a prescriber and including the reference "SLS", or*

*(iii) an order for a restricted availability appliance, signed by a prescriber and including the reference "SLS"; or*

(b) *subject to sub-paragraph (4), P receives from the Electronic Prescription Service an electronic prescription form which contains an order of a kind specified in paragraph (a) (i) to (iii) and—*

*(i) any person requests the provision of drugs or appliances in accordance with that prescription, or*

*(ii) P has previously arranged with the patient that P will dispense that prescription on receipt, P must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as P supplies in the normal course of business*

(3) *Subject to the following provisions of this Part, where—*

(a) *any person presents to P a non-electronic repeatable prescription which contains—*

*(i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971(2), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(3) (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a prescriber,*

*(ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in*



*Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber and including the reference "SLS",*

*(iii) an order for appliances, not being restricted availability appliances, signed by a prescriber, or*

*(iv) an order for a restricted availability appliance, signed by a prescriber, and including the reference "SLS", and also presents an associated batch issue; or*

*(b) P receives from the Electronic Prescription Service an electronic repeatable prescription which contains an order of a kind specified in paragraph (a) (i) to (iv) and—*

*(i) any person requests the provision of drugs or appliances in accordance with that repeatable prescription, or*

*(ii) P has previously arranged with the patient that P will dispense that repeatable prescription on receipt,*

*P must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as P supplies in the normal course of business.*

3.10 These were answered briefly in previously submitted SOPs (Appendix A-Assembling and labelling prescriptions and Appendix ) but [you] are write [sic] it was missing some information so apologies for that, please now see attached SOPs Appendix V-Dispensing and Appendix W-Repeat dispensing which fully answer this regulation.

The Applicant has not explained how it proposes safely and effectively to receive requests from prescribers for urgent supplies of drugs and appliances without a prescription.

*Urgent supply without a prescription*

*6.—(1) This paragraph applies where, in a case of urgency, a prescriber requests an NHS pharmacist (P) to provide a drug or appliance.*

*(2) P may provide the drug or appliance requested before receiving a prescription form or repeatable prescription in respect of that drug or appliance, provided that—*

*(a) in the case of a request for a drug, the drug is neither—*

*(i) a Scheduled drug, nor*

*(ii) a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001 (which relate to controlled drugs excepted from certain prohibitions under the Regulations); and*

*(b) in the case of a request for a drug or an appliance, the prescriber undertakes to—*

*(i) give P a non-electronic prescription form or non-electronic repeatable prescription in respect of the drug or appliance within 72 hours of the request being made, or*

*(ii) transmit an electronic prescription to the Electronic Prescription Service within 72 hours of the request being made*

- 3.11 [NHS England was] right - an SOP for urgent supplies was not supplied but this has now been supplied. Please see attached SOP Appendix X-Urgent supplies. This explains how the Applicant will deal with an emergency supply. Please also note that nowadays the majority of scripts are electronic so the need for emergency supplies has greatly reduced but nevertheless it is still sometimes needed and for this reason it has included the SOP for this.

The Applicant has provided no information regarding paragraph 7(3) of schedule 4 of the regulations.

*Preliminary matters before providing ordered drugs or appliances*

*(3) Before providing any drugs or appliances in accordance with a prescription form or a repeatable prescription, P must ask any person who makes a declaration that the person named on the prescription form or the repeatable prescription does not have to pay the charges specified in regulation 3(1) or (1A) of the Charges Regulations(4) (supply of drugs and appliances by chemists) by virtue of either—*

*(a) entitlement to exemption under regulation 7(1) of the Charges Regulations(5) (exemptions); or*

*(b) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations(6) (entitlement to full remission and payment),*

*to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of sub-paragraph (a), (c), (d), (e), (f) or (g) of regulation 7(1) of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 5(1)(e) or (2) of the Remission of Charges Regulations, and at the time of the declaration P already has such evidence available to P.*

- 3.12 This information has been mentioned briefly in Appendix A but the Applicant has now attached an SOP which was not attached before giving full details of the exact process and hope it is to [NHS Resolution's] satisfaction (Appendix V-Dispensing). In summary [the Applicant] asks [the] patient to send proof of exemption securely and ascertain this and tick the back of the script.

The Applicant has provided limited information regarding paragraph 8(15) of schedule 4 of the regulations.

*Providing ordered drugs or appliances*

*(15) P must provide any drug which P is required to provide under paragraph 5 in a suitable container.*

- 3.13 The Applicant previously did not send this SOP, but it is now attached (Appendix V-Dispensing). This is under 'procedure' and bullet point 9. This mentions that everything should be dispensed in a suitable container such as glass bottles for liquids and plastic bottles for split quantities tablets or capsules if necessary. Please refer to the appendix for full details.

The Applicant has provided no information regarding paragraph 10(1) of schedule 4 of the regulations.

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

*10.—(1) In connection with the services provided under paragraph 4, an NHS pharmacist (P) must—*

*(a)ensure that appropriate advice is given to patients about any drugs or appliances provided to them—*

*(i)to enable them to utilise the drugs or appliances appropriately, and*

*(ii)to meet the patient's reasonable needs for general information about the drugs or appliances;*

*(b)provide appropriate advice to patients to whom they provide drugs or appliances on—*

*(i)the safe keeping of the drugs or appliances, and*

*(ii)returning unwanted drugs or appliances to the pharmacy premises for safe destruction;*

*(c)when providing drugs to patients in accordance with a repeatable prescription, provide appropriate advice in particular on the importance of only requesting those items which they actually need;*

*(d)when providing appliances to patients in accordance with a prescription form or repeatable prescription—*

*(i)provide appropriate advice in particular on the importance of only requesting those items which they actually need, and*

*(ii)for those purposes, have regard to the details contained in the records maintained under paragraph (f) in respect of the provision of appliances and prescribing pattern relating to the patient in question;*

*(e)provide a patient with a written note of any drug or appliance which is owed, and inform the patient when it is expected that the drug or appliance will become available;*

*(f)keep and maintain records—*

*(i)of drugs and appliances provided, in order to facilitate the continued care of the patient;*

*(ii) in appropriate cases, of advice given and any interventions or referrals made (including clinically significant interventions in cases involving repeatable prescriptions), and*

*(iii) of notes provided under sub-paragraph (e);*

*(g)undertake appropriate training in respect of repeat dispensing, having regard to any recommendations in respect of such training set out in the Drug Tariff;*

*(h)if P takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;*

*(i)if P provides a drug or appliance under an electronic prescription, provide the patient, if the patient so requests, with a written record of the drugs or appliances ordered on that prescription and, in the case of an electronic repeatable prescription, of the number of occasions on which it can be dispensed;*

*(j)maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied);*

*(k) destroy any surplus batch issues relating to drugs or appliances—*

*(i) which are not required, or*

*(ii) where a patient is refused the drugs or appliances pursuant to paragraph 9;*

*(l) ensure that where a person is refused drugs or appliances pursuant to paragraphs 9(1)(b), (2), (3) or (4), the patient is referred back to the prescriber for further advice;*

*(m) where a patient is provided with drugs or appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification;*

*(n) notify the prescriber of any refusal to provide drugs or appliances pursuant to paragraph 9(4);*

*(o) when providing appliances, provide a patient with a written note of P's name, address and telephone number; and*

*(p) when providing specified appliances, comply with the additional requirements set out in paragraph 12.*

3.14 The Applicant once again did not send this SOP, but [has] now attached it to this appeal, please see attached Appendix Y-further activities linked to dispensing. This SOP covers all the above-mentioned issues. Please note as per SOP initially submitted (Appendix D-Dispensing appliances) the Applicant will not be dispensing appliances as part of their usual business activities so [NHS Resolution] will see that appliances are not mentioned in this SOP.

3.15 The Applicant hopes now that everything they have submitted is to [NHS Resolution's] satisfaction and the Applicant has demonstrated that it can follow NHS guidance on running a distance selling pharmacy without breaching NHS guidelines. If [NHS Resolution] has any further questions, please do let the Applicant know and they will be more than happy to supply any information that may be needed.

In support of the appeal the Applicant included a copy of their SOPs as well as further information which had been sent to NHS England under cover of a letter dated 11 November 2019. The letter stated:

3.16 In addition to the information submitted in the application, the Applicant would also like to include the following supportive evidence emphasising their understanding and dedication to the NHS essential services and that they have all the required knowledge and understanding to deliver an uninterrupted service. Listed below are the NHS essential services for any community pharmacy together with evidence in support of the service: -

3.17 **Dispensing Medicines:** The pharmacy staff abiding by their professional roles as technicians and pharmacists will supply with reasonable promptness medicines and appliances ordered on NHS prescriptions with the correct information and advice whilst ensuring product integrity and quality; thus ensuring effective use by patients/carers and maintaining all relevant records. Please refer to Appendices A, B, C, V, and X attached.

3.18 **Dispensing Appliances:** When an NHS prescription is obtained for an appliance, it will be forwarded with the patient's consent to a Dispensing Appliance Contractor (DAC) such as NWOS. This is to ensure that all aspects of this essential service are. Please refer to Appendix D for full details.

3.19 **Repeat Dispensing:** Repeat prescriptions will be dispensed as per repeat dispensing sop with the addition of storing the documentation if the patients require so. Supply will

only be made when medication is required and when no changes have occurred that would require referral back to the GP. Please refer to appendix E and W for a complete outline of the repeat dispensing process.

- 3.20 **Clinical Governance:** A part of this service is publicly advertised directly to the Applicant's patients and the public through the website ([www.britishchemist.co.uk](http://www.britishchemist.co.uk)) in the 'About Us' section and distributing leaflets to patients. It covers aspects such as the practice leaflet, satisfaction surveys and the complaints system. Other parts of the service are covered by SOPs some of which are included in the following appendices (attached). Patient satisfaction surveys together with pharmacy clinical audits and Information governance will be carried out on an annual basis according to the approved particulars of the Department of Health. The Applicant would like to point out here with regard to the premises; that no patients will be allowed into the pharmacy under any circumstances including when providing MURs. Since it is compulsory for distance selling pharmacies to obtain consent from the CCG for each patient on each separate occasion to provide MURs; consent will be only obtained for either phone-call MURs or off-site MURs. Hence, no consultation room is required. Please refer to appendices F, G, GA, H, I, J, K, L, M, N and O.
- 3.21 **Public Health:** As an Online pharmacy, promoting healthy lifestyles is extremely important. This is mainly done through the website or when distributing NHS leaflets to patients. The Well-Being section of the website provides public health advice and support and targets the main health campaigns as set out by NHS England. Prescription-linked interventions will be spotted in pharmacy and patient contact will be made as according to SOP. Please refer to Appendix P.
- 3.22 **Disposal of Unwanted Medicines:** Pharmacies are obliged to accept back unwanted medicines from patients. This is something that the Applicant feels strongly about and adhere to as per SOP attached.
- 3.23 However please note the following; under the specification, no pharmacy is obliged to collect waste medicines from patients' homes. Nor can patients return medicines to the pharmacy premises as it would constitute a breach of service contract. As such no solution is presented by NHS England to this dilemma. The Applicant's solution is as follows; in all publicly available material it will be stated that patients have the right to return their unwanted medicines to any local NHS pharmacy even if that pharmacy did not initially dispense these medications. This will be particularly important and will be emphasised upon for patients outside of the Applicant's vicinity. Secondly, once a license is granted by NHS England, the Applicant's drivers will collect waste medicines from patients' homes in the vicinity. However, and as per the Government Environment Agency, the Applicant will obtain an upper-tier 'Waste Carriers License' for their drivers to transit waste medicines from patient's homes to the pharmacy. As mentioned, pharmacies are not obliged to collect medication, however, the Applicant feels that it is an important service to offer and so this license will be obtained once NHS license is granted. The waste carriers license is renewable every three years. Appendix Q
- 3.24 **Signposting:** This is a day-to-day activity in the pharmacy. All patients that cannot be provided with adequate help and support will be referred or signposted to other health and social care providers or support organisations who may be able to assist the person accordingly. The pharmacist will make a note of the referral if deemed necessary. Signposting will be carried out equally when approached either by email or on the phone. The Applicant will have a list of local services available and if the patient is not a local, then the Applicant can assist them by pointing out those services closest to them through the NHS Choices website or the NHS 111 service if necessary. The Applicant also has links to main health topics to the NHS Choices website through the website. Appendix R.
- 3.25 **Support for Self-Care:** The Applicant will provide maximum support from the pharmacy to enable people to care for themselves or their families. There is a range of topics ranging from long-term conditions to minor ailments on the website in the well-

being section that aims to provide information and advice in support of patient's conditions. This information is also linked to the NHS Choices website for up to date information and support and also if the patient would like more in-depth scientific knowledge. The support for self-care will also be provided opportunistically if a patient or carer telephones the pharmacy for advice. A note will be made of any advice given to patients whether online or over the phone if deemed necessary. This service intertwines of course with signposting and public health promotion. Please refer to Appendix S.

- 3.26 **Emergency supplies:** In regard to the supply of emergency medications. The pharmacist will at the request of a patient (or in pandemic situations, a representative of a patient), assess whether there is an urgent need for their medicine, in circumstances where it is impracticable for the patient to obtain a prescription before the next dose is due. If an emergency supply is necessary, the pharmacist shall make a supply, in accordance with the Human Medicines Regulations, maintaining a record of the supply and labelling the container appropriately. The pharmacy will provide a supply, of up to 30 days for UK residents and to cover the duration of stay in the county for visitors, of medicines that the patient routinely has on an NHS repeat prescription from their GP. Please refer to appendix X.
- 3.27 There are also certain regulations that the Applicant must satisfy which are Regulations 25 and 64 of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. Regulation 25 and 64. Please note that the pharmacy premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Applicant will also be open 5 days a week Monday to Friday 9 am to 5 pm with a pharmacist present on-site to ensure an uninterrupted provision of essential services to any patient anywhere in England who requests those services. Please note as mentioned already that these essential services are provided without face-to-face contact as mentioned in the SOPs. NHS services are provided to anyone in England and all marketing material including the website will reflect this important point. The Applicant is certain that all aspects of both these regulations are fully satisfied and complete. Appendix T and U.
- 3.28 The Applicant has made every effort to abide by all the NHS terms of service and can adapt fully to them.
- 3.29 The attached appendices are not the full list of SOPs but are what the Applicant feels are most relevant to the application. Please let [the Applicant] know if [NHS Resolution] requires anything else and [the Applicant] will be more than happy to provide this information. If [NHS Resolution] has any suggestions or queries, please do not hesitate to contact [the Applicant].
- 3.30 Furthermore, the Applicant would like to add that providing non face to face contact on the premises is becoming more widespread, and not just for pharmacy businesses but for all kinds of businesses which they are sure [NHS Resolution] will agree, especially since the covid-19 pandemic where the vulnerable had to self-isolate and keep safe and who are the biggest population who use pharmacies. The Applicant completely understands that [NHS Resolution] may have a quota because the pharmacy market is becoming over saturated but those who do not succeed in this field will close down and the NHS does not lose money for this especially since the NHS stopped paying practice payments and cut the NHS budget and now pharmacies only get paid for what they dispense. The more competition there is, the better the NHS service patients will receive, and the Applicant considers this healthy business in which the patients have lots of choice.
- 3.31 Additionally, with the introduction of electronic prescribing (this now includes controlled drugs) even brick and mortar pharmacies are now seeing patients a lot less as the needs to attend a pharmacy has dramatically reduced.

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. 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.

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

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

#### 4.2 BOOTS UK LTD

4.2.1 Boots UK Ltd have no further comments to make but respectfully ask that NHS Resolution inform it of the decision in due course and Boots would wish to attend an oral hearing should it be deemed necessary to hold one.

#### 4.3 LLOYDS PHARMACY

4.3.1 Lloyds have included with this response a copy of the representations they sent to NHS England as part of the initial consultation. Lloyds Pharmacy ask Primary Care Appeals to review all the evidence provided by the Applicant in accordance with the criteria set out in Regulation 25 and the conditions set out in Regulation 64.

In a letter addressed to NHS England dated 14 January 2020, Lloyds Pharmacy stated:

4.3.2 It is noted this is an application to provide Distant Selling Pharmaceutical Services. With regards to deliveries, the Applicant provides brief details of procedures for 'non local' deliveries but there is no explanation of what 'non local' is. Neither does there appear to be any procedures for 'local' deliveries.

4.3.3 For Distant Selling applications all matters relating to Regulation 25 must be considered as well as the conditions set out in Regulation 64.

### 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 application form the reasoning given by the Applicant as to why Regulation 31 is not applicable. NHS England, in its decision, noted that there were no pharmacies listed at the proposed premises or adjacent to the proposed premises and the Committee noted that this had not been disputed by parties. Based upon the information before it, the Committee considered that it was not required to refuse the application under the provisions of Regulation 31.

#### **Regulation 25**

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

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

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

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

*in respect of pharmacy premises that are distance selling premises.*

(2) The NHSCB must refuse an application to which paragraph (1) applies—

(a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and

(b) unless the NHSCB is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—

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

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



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

***Additional information to be included with excepted applications***

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

***Nature of details to be supplied***

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

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

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

**Regulation 25(1)**

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

**Regulation 25(2)(a)**

- 6.11 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states "There are no providers of primary medical services in the same site or in the same building therefore this point is not applicable." The Committee noted that this had not been disputed by parties. 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 original application and the Standard Operating Procedures (SOPs) which the Applicant has prepared or commissioned. The Committee noted the applicant had been provided with the opportunity to provide all relevant information to support its application.
- 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 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. The Committee noted the Applicant, in its appeal, stated "*The Applicant completely understands that [NHS Resolution] may have a quota because the pharmacy market is becoming over saturated but those who do not succeed in this field will close down and the NHS does not lose money for this especially since the NHS stopped paying practice payments and cut the NHS budget and now pharmacies only get paid for what they dispense.*" The Committee reminded itself that the decision to grant or refuse the application will be based on the information provided and that no such quotas for the granting of applications (as referred to by the Applicant) existed.
- 6.17 The Committee noted in the information provided, the Applicant states in the application:
- 6.17.1 "*There will be a registered pharmacist on-site throughout the opening hours to ensure an uninterrupted service.*"
- 6.18 The Committee noted this is reiterated in the Applicant's appeal. The Applicant also provided its SOP entitled "Responsible Pharmacist RP1" which details the procedure to be followed and known by the responsible pharmacist. The Committee noted point 7 of this SOP which states:
- 6.18.1 "*If the Responsible pharmacist is not contactable during the absence then he/she will arrange for another responsible pharmacist to be available and that persons contact details will be available to staff.*"
- 6.19 The Committee noted the Applicant, in its application, states:
- 6.19.1 "*Secondly, the Applicant will make it very clear to all their patients they are a delivery only pharmacy meaning they are not allowed to come and collect their prescriptions from them and if they intend to do that then the Applicant will let them know that the services are not suitable for them and they will be signposted to the closest retail pharmacy that is not a distance selling pharmacy. This will be reinforced in the sign-up forms where the Applicant will clearly state in the form that they are an online pharmacy only and they DO NOT allow for face to face contact on the premises or within the vicinity of the*

*premises and if they have any queries they must contact either by phone, email or via the website. ....*

6.19.2 *The Applicants robust working practices and operating procedures ensure 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 their staff."*

6.20 The Committee noted that in its appeal, the Applicant had provided its SOP entitled "Forbidden Face to Face Contact". The purpose of this SOP is:

6.20.1 *"To underline the importance of this issue to both patients and staff alike. That no face-to-face contact is permissible under any circumstances on the pharmacy premises."*

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

6.22 The Committee noted in the information provided, the Applicant, in its application form, states:

6.22.1 *"As the Applicant is an online pharmacy, they will be providing their services nationwide and not locally and so do not intend on competing in the local market. ....*

6.22.2 *All essential service will be available throughout the United Kingdom so no discrimination for those wanting the service no matter where they live."*

6.23 In its appeal, the Applicant states:

6.23.1 *"Please note the Applicant has no intention of operating locally because the area they are in is saturated and so that is why they applied for a distance selling pharmacy, so they can aim to operate nationally. ....*

6.23.2 *The Applicant will not refuse any prescriptions that come their way, no matter where the patients live. ....*

6.23.3 *A non-local delivery is delivering nationwide to any patient in the UK that opts in to receive the service."*

6.24 The Applicant provided some of its SOPs in support of its appeal. The Committee noted the SOP entitled "Repeat Dispensing" states under the heading "SCOPE":

6.24.1 *"The procedure covers repeat dispensing operating between the pharmacy, participating local surgeries and consenting patients."*

6.25 Further, the Committee noted a leaflet entitled "British Chemist Will you help us to help you?" This leaflet invites general comments and suggestions about ways the pharmacy can improve its services. The leaflet states:

6.25.1 *"You may also seek advice from the local Patient Advice and Liaison Service (PALS). PALS are not part of the complaints procedure but they might be able to resolve your concerns informally or they can tell you more about the complaints procedure and independent complaints advocacy services."*

6.26 The Committee was mindful that the leaflet provided contact details for the Central Middlesex Hospital which is the service for the local area.

- 6.27 The Committee also noted a reference in the SOP entitled “For infection control in the pharmacy” there is a box in the flow chart which states:
- 6.27.1 *“If any testing at patient’s home for diabetes or cholesterol testing:*
- 6.27.1.1 *Member of staff should be suitably trained and wear gloves and apron.....*
- 6.27.1.2.... *Speak to GP, PCT or superintendent before starting a service.”*
- 6.28 The Committee noted no further detail was provided to indicate how this service could be provided nationwide at a patient’s home. Further, the Committee was of the view that references to participating local surgeries and the local PALS service within the SOP documentation did not support the statements made by the Applicant in its application and appeal. Therefore the Committee was not satisfied that the provision of essential services would be available to persons anywhere in England.
- 6.29 The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.
- 6.30 The Committee considered each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations (“Terms of Service”) in turn.
- 6.31 The Committee paid particular attention to the following aspects of the essential services, which it considered were more difficult to provide safely and effectively in a distance selling context:
- 6.31.1 Dispensing of drugs and appliances
- 6.31.2 Urgent supply without a prescription
- 6.31.3 Preliminary matters before providing ordered drugs or appliances
- 6.31.4 Providing ordered drugs or appliances
- 6.31.5 Refusal to provide drugs or appliances ordered
- 6.31.6 Further activities to be carried out in connection with the provision of dispensing services
- 6.31.7 Disposal service in respect of unwanted drugs
- 6.31.8 Promotion of healthy lifestyles
- 6.31.9 Prescription linked intervention
- 6.31.10 Public health campaigns
- 6.31.11 Signposting
- 6.31.12 Support for self-care.
- 6.32 The Committee was of the opinion that the procedures adopted by the pharmacy were not likely to secure the safe and effective provision by the Applicant of the following essential services:

**Providing ordered drugs or appliances**

- 6.33 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).
- 6.34 In its application, the Applicant stated:
- 6.34.1 *"Delivery of ambient medication will be provided by the Applicant's drivers, UPS or FedEx and all temperature sensitive medication will be delivered via igloo logistics in their temperature-controlled vehicles. All deliveries will be signed for so the Applicant has a trace and proof of postage and delivery."*
- 6.35 The Committee noted that with its appeal, the Applicant had provided some SOPs. The Committee noted in the SOP entitled "Dispensing Process", under the heading "Bagging up of dispenses items" points 7 to 9 state:
- 6.35.1 *"Controlled drugs and Fridge items will have special handling requirements. Controlled drugs are sent separately and must be signed for (see Appendix U) upon delivery and Fridge items must be sent via a temperature regulated logistics (see Appendix U).*
- 6.35.2 *Until fridge items are ready to be collected by our drivers or the courier they will be labelled and put back in the fridge*
- 6.35.3 *Until Controlled drugs are ready to be collected by our drivers or the courier they will be labelled and put back in Controlled drug cabinet."*
- 6.36 The Committee noted the SOP entitles "Cold chain medicines". The purpose of this SOP is *"to adopt a procedure for the receipt, checking, storage and delivery of cold chain medicines."* Under the heading "Home delivery of Fridge lines" points 24 to 26 state:
- 6.36.1 *"Delivery routes should be planned so as to ensure fridge lines are delivered as soon as possible and the cold chain is maintained. If possible, a cool box should be used to maintain low temperatures during transit for local deliveries by our own drivers and if anywhere else we will use igloo thermo logistics for transportation of our fridge lines to our patients and we will ask for receipts showing current temperatures in their vehicles upon collection of stock.*
- 6.36.2 *The recipient should be reminded to follow the manufacturer's instructions on domestic storage of the medicine.*
- 6.36.3 *If a fridge line cannot be successfully delivered for any reason then it must be returned to the pharmacy as soon as reasonably possible. The pharmacist must be satisfied that the cold chain has been maintained.*
- 6.37 The Committee noted there was reference to controlled drugs in the SOP entitled "Emergency supply at request of prescriber" which states what it can and cannot prescribe regarding CDs. There is a section at point 9 of the SOP entitled "Owings Procedure" which makes reference to another SOP CD1. The Committee noted it was not provided with a copy of SOP CD1. The SOP entitled "Non-local Delivery Service" states:
- 6.37.1 *"Controlled drugs are sent separately to other medications. Must obtain patient signature as consent to act as representative prior to any deliveries for controlled drugs."*
- 6.38 The Committee considered the cold chain information and had expected a more detailed explanation such as how the Applicant would check the temperature of cold chain medication to ensure it was maintained throughout its journey or what it would

do if the temperature was compromised during transit. The Committee was of the view that the information provided fell short of satisfying the Committee that the “cold chain” would be maintained throughout the delivery.

- 6.39 The Committee was of the view that the Applicant had not provided assurance as to how controlled drugs would be kept secure during transit, for example being held in a lockable storage facility inside the delivery vehicle.
- 6.40 The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.
- 6.41 The Committee considered whether the Applicant had explained what containers will be “suitable” for posted/delivered items.
- 6.42 In its SOP entitled “Dispensing process”, point 9 of the procedure states:
- 6.42.1 *“Ensure everything is dispensed in a suitable container, either in original manufacturer packaging or if smaller quantities then in a plain cardboard box or if loose tablets/capsules then in a dispensing bottle with a child resistant cap and the expiry date and batch details are recorded on the container and ensure Patient Information Leaflets (PILs) are always included.”*
- 6.43 Point 6 of the “bagging up of the dispenses items states:
- 6.43.1 *“For any items that will be posted via a courier, they must be put in cardboard boxes and not just dispensing bags as dispensing bags are likely to rip and medications may fall out.”*
- 6.44 The Committee was of the view that whilst the Applicant stated it would use suitable containers, it did not describe what the suitable containers would be. The Committee would expect a more detailed description to be given, as medication in the form of blister pack tablets would need different outer packaging to medication stored in a glass bottle for example.
- 6.45 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.

#### **Additional Considerations**

- 6.46 The Committee note that in its application the Applicant has stated it does 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 appliances.
- 6.47 The Committee noted that NHS England, in its decision had not been satisfied regarding the following points. However on review of the additional documentation provided with the appeal, NHS England, in its representations no longer objected to these points. The Committee reviewed each point in turn to ensure it too was satisfied with the compliance of each point.

#### **Dispensing of drugs and appliances**

- 6.48 The Committee considered whether the Applicant had explained how non-electronic prescriptions will be presented by the patient and how products will be provided.
- 6.49 The Applicant, in its appeal states the information is in the SOP entitled “Dispensing Process” and SOP entitled “Repeat Dispensing”. The Committee noted the scope for the SOP “Dispensing process” states:

6.49.1 *"This procedure covers the entire process of dispensing from acceptance of a prescription electronically or non-electronically by post, to the final process where it goes out to patients via our own drivers or courier."*

6.50 The Committee noted that the SOP "Repeat dispensing" states:

6.50.1 *"... Explain to the patient (over the phone) the benefits of the RD/eRD service and gain their consent before referral."*

6.50.2 *Complete an NHS eRD service referral form and get patient to sign the form and post back/email back to pharmacy NHS email."*

6.50.3 *Send the completed NHS electronic repeat dispensing service referral form to the GP via post or email. ...."*

6.51 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 prescription**

6.52 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

6.53 In its appeal, the Applicant states:

6.53.1 *"The pharmacist will at the request of a patient (or in pandemic situations, a representative of a patient), assess whether there is an urgent need for their medicine, in circumstances where it is impracticable for the patient to obtain a prescription before the next dose is due. If an emergency supply is necessary, the pharmacist shall make a supply, in accordance with the Human Medicines Regulations, maintaining a record of the supply and labelling the container appropriately. The pharmacy will provide a supply, of up to 30 days for UK residents and to cover the duration of stay in the county for visitors, of medicines that the patient routinely has on an NHS repeat prescription from their GP. Please refer to appendix X."*

6.54 The Applicant has also provided its SOP entitled "Emergency supply at request of prescriber". The Committee noted the purpose of this SOP is:

6.54.1 *"To comply with the law and ethics of issuing emergency medication."*

6.54.2 *To ensure the patients' needs are met."*

6.54.3 *To ensure records for the supply are kept."*

6.54.4 *To ensure the prescription is received for this supply if appropriate."*

6.55 The Committee noted the procedure set out in the SOP and was 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**

6.56 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.

- 6.57 In its appeal, the Applicant states it will ask the :
- 6.57.1 *“patient to send proof of exemption securely and ascertain this and tick the back of the script.”*
- 6.58 The Applicant also refers to its SOP entitled “Dispensing Process” which states at point 1 of the procedure:
- 6.58.1 *“If exempt then ask patient to email proof of their exemption to our NHS email otherwise if they say they do not have proof but insist they are exemption then ask them which is their exemption and tick this along with evidence not seen at the back of the prescription. If evidence is seen and you are satisfied it is genuine then record this on their PMR and write date of expiration of their exemption and check this every time before any medications go out to make sure their exemption is still valid. If in any doubt about the validity of their exemption, then call the NHS and check.”*
- 6.59 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.

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

- 6.60 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 a 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.
- 6.61 In its appeal, the Applicant had stated:
- 6.62 **“Repeat Dispensing:** *Repeat prescriptions will be dispensed as per repeat dispensing SOP with the addition of storing the documentation if the patients require so. Supply will only be made when medication is required and when no changes have occurred that would require referral back to the GP. Please refer to appendix E and W for a complete outline of the repeat dispensing process.”*
- 6.63 The Committee reviewed the SOP entitled “Repeat dispensing”. The Committee noted the SOP states under point 1 of the procedure:
- 6.63.1 *“Once a patient signs up to our service and presents with a repeat prescription, consider if they are suitable for the repeat dispensing (RD) service*
- 6.63.2 *The eligibility criterial for the RD or eRD (Electronic Repeat Dispensing) the patient must.*
- 6.63.2.1 *Receive a repeat prescription*
- 6.63.2.2 *Suffers from a long-term medical condition that requires stable therapy*
- 6.63.2.3 *Is in receipt of medications that remain stable between reviews with the GP*
- 6.63.2.4 *Can self-manage their medical condition*
- 6.63.3 *Explain to the patient (over the phone) the benefits of the RD/eRD service and gain their consent before referral.*



- 6.63.4 *Complete an NHS eRD service referral form and get patient to sign the form and post back/email back to pharmacy NHS email*
- 6.63.5 *Send the completed NHS electronic repeat dispensing service referral form to the GP via post or email.*
- 6.63.6 *Before issuing of the RD prescription the pharmacist must ensure:*
  - 6.63.6.1 *Patient is not suffering any side effects which may mean the medicines need reviewing by the prescriber and a likely change in medication*
  - 6.63.6.2 *Ensure patient is stable on their medications*
  - 6.63.6.3 *No changes in the patient's health that can also lead to a change*
  - 6.63.6.4 *Repeatable prescriptions must be for the first time within six months of the authorising date. ....*
- 6.63.7 *.... Once the first ever batch of the repeat dispensing is fulfilled and the medications are posted to the patient, a follow up call by the pharmacist is to be made to ensure the patient fully understands the RD process.*
- 6.63.8 *Paper repeat prescription forms are kept in a filing cabinet alphabetically whilst electronic ones will sit in the system (the PMR) until they are requested by the patient and ready for dispensing. A record is kept of each time a prescription is dispensed.*
- 6.63.9 *Confirm with the patient which items they need. Additionally, check with the patient if there have been any changes in their medications or health since their medications were last dispensed.*
- 6.63.10 *A referral or intervention should be made by the pharmacist where there are clinically significant changes. Ensure patient is kept in the loop at all the stages of the intervention process and everything is recorded.*
- 6.63.11 *Following the relevant SOPs to dispense the RD or eRD until the last stage of delivery to the patient via our drivers or courier company.*
- 6.63.12 *Advise patient via telephone, or secure email when their next RD is due.*
- 6.63.13 *Record the date of supply and any other relevant information gained from the patient such as Non dispensed (ND) items, side effects and interventions.*
- 6.63.14 *Ensure the prescription is endorsed correctly and claimed for correctly.*
- 6.63.15 *Check the patient's exemption status at each dispensing. This can be updated on the pharmacy PMR software.*
- 6.64 *The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.*

## **Summary**

- 6.65 *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.*

- 6.66 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).
- 6.67 The Committee noted that on appeal, the Applicant had provided additional information which NHS England had not seen prior to its deliberation of the application. In those circumstances as the Committee has reached different conclusions to NHS England in light of the additional information which all parties reviewed during the appeal process, it determined that the decision of NHS England must be quashed.
- 6.68 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.
- 6.69 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.
- 6.70 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 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 satisfied that all essential services were likely to be secured without face to face contact;
  - 7.2.3 The application is refused.

**Alison McCafferty**  
**Case Manager**  
**Primary Care Appeals**

A copy of this decision is being sent to:

Mojji Ls Ltd  
Lloyds Pharmacy  
PCSE on behalf of NHS England - London Region Area Team