

24 January 2019

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**REF: SHA/21019**

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**APPEAL AGAINST SOUTH EAST AREA TEAM, NHS COMMISSIONING BOARD "NHS ENGLAND" DECISION TO GRANT AN APPLICATION BY MANEPH RESOURCES LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT OFFICE SUITE N, FIRST FLOOR, THE KIDLINGTON CENTRE, HIGH STREET, KIDLINGTON, OX5 2DL UNDER REGULATION 25**

1 **Outcome**

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

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Advise / Resolve / Learn

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## 1 The Application

By application dated 10 June 2018, Maneph Resources Ltd ("the Applicant") applied to NHS Commissioning Board ("NHS England") for inclusion in the pharmaceutical list at Office Suite N, First Floor, The Kidlington Centre, High Street, Kidlington, OX5 2DL under Regulation 25. In support of the application it was stated:

1.1 In response to "If you are undertaking to provide appliances, specify the appliances that you undertake to provide (or write 'none' if it is intended that the pharmacy will not provide appliances)" the Applicant stated

1.1.1 Not Applicable.

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

1.2.1 Not Applicable.

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

1.3.1 Not applicable.

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 The Applicant attached some relevant SOPs to this application form, but summarises the key points hereunder. Please note that details are in the full suite of SOP and the following provide an overview of the pharmacy procedures to ensure safe, effective and uninterrupted provision of services to persons anywhere in England without face-to-face contact.

1.6 Premises

- 1.6.1 The premises are in an office block and there are no providers of medical, dental or pharmaceutical services (with or without a patient list) within the same building. A pharmacist will always be present during contracted opening hours and each pharmacist will log on to the Pharmacy computer system as well as the EPSR2 systems to keep contemporaneous records of the pharmacist(s) present.
- 1.7 Uninterrupted Provision of Services
- 1.7.1 A pharmacist will always be present to ensure uninterrupted provision of essential services, and a log of the Responsible Pharmacist will be kept to demonstrate this.
- 1.7.2 The Applicant recognises that the main issue with a DSP is the provision of Essential services without public contact; the pharmacy is situated on an upper floor of an office building and there will be no signage so as to minimise the chances of inadvertent face to face contact. Moreover, there is no shop front which might inadvertently encourage such communication.
- 1.8 Advice & Counselling
- 1.8.1 The Applicant plans to deliver medication advice and counselling, and indeed opportunistic advice via numerous methods; secure telephone, webcam and visual call facilities such as Skype and Facetime, WhatsApp video call, etc. (where patients have access to such facilities and consent to communicating in this way) or through the website. The simultaneous delivery of leaflet information/advice via mail or via delivery person along with patients' medication maybe utilised to reinforce previous counselling advice. A delivery person will NOT give opportunistic advice or guidance. Any guidance on medication that is particularly important will be made via the communication methods stated above. Where there is need to pass critical information to the patient, the Applicant will not dispatch medicines of this nature until the Pharmacist is suitably satisfied the information has been delivered to the patient and they have thoroughly understood it.
- 1.9 Lifestyle Advice
- 1.9.1 The website will provide the opportunity for patient's to consent to being contacted periodically regarding life style advice, if they state yes, the Applicant will put them on a mailing list of people who will receive periodic health information bulletins.
- 1.10 Verification of Declarations of Exemptions
- 1.10.1 When patients sign up to our service they will be asked to tick their exemption on the form. The patients will then be asked to send a picture of their exemptions cards and send via secure email, WhatsApp, fax or Free post envelopes.
- 1.11 Providing a National Service
- 1.11.1 Information will be readily available on the website to demonstrate that the Applicant provides a national service. The pharmacy and indeed the website will be registered with GPhC and display the approved logo.
- 1.11.2 With EPS being rolled out nationwide patients can easily nominate the pharmacy for their GP to send their scripts to the Applicant. The prescription once dispensed will be sent, at no cost to either the patient or the NHS, via a reputable courier company in an unmarked box or suitable packaging.

## 1.12 Clinical Governance

1.12.1 A clinical governance lead will be appointed to oversee all the aspect of clinical governance in the pharmacy. The Applicant intends to adhere to stipulated national guidelines. The Applicant intends to function similar to majority of other internet pharmacies providing pharmaceutical services via this method. All pharmacists will be completing their CPD, now mandatory for revalidation. The Applicant will carry out clinical audit appropriate to our pharmacy annually. The annual patient survey will be completed via the website. The Applicant will gain consent of patients who use the website prior to them filling out the survey.

## 1.13 Deliveries

1.13.1 Deliveries will be via an appropriate courier service at no extra cost to either the patient or the NHS in a manner that there is an audit trail.

1.13.2 The partner organisations including the courier company will sign service level agreements that cover data protection, secure delivery of controlled drugs and maintenance of the cold chain for thermolabile items.

1.13.3 All delivered medications will arrived in plain tightly packed and tamper evident parcels. All that will be present on the packaging will be the patient's name and address.

## 1.14 Management of Waste Medicines

1.14.1 On client demand, the Applicant will nationally via their courier offer to collect and safely dispose of any unwanted appliances and medicines in a manner that an audit trail is kept. DOOP bins will be in the office to store waste in time for the waste disposal contractor. Returned medicines will be stored separately. Schedule 2 and 3 drugs will stored securely as per safe custody regulations until denatured by the pharmacist, and the Applicant would be registering with the Environment Agency so as to meet our statutory obligations.

1.15 The relevant SOPs that were provided with the Application form can be found at Appendix A.

1.16 The Applicant subsequently amended their application form in response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant stated "we erroneously stated 'not applicable', an invalid option for this question. We have amended that to read 'Drug Tariff part IX except items that require measuring or fitting'"

1.17 The Applicant provided additional SOPs to NHS England in their response to the representations received. These were not circulated by NHS England but have been circulated with the appeal and can be found at Appendix B.

## 2 The Decision

NHS England considered and decided to grant the application. The decision letter dated 8 October 2018 states:

2.1 NHS England has considered the above application and is writing to confirm that it has been granted. Please find enclosed a document detailing the approval of the application.

- 2.2 As [your] application is in respect of distance selling premises, by virtue of regulation 64(3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, it has been granted subject to:
- 2.2.1 you must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises;
  - 2.2.2 the means by which you provide pharmaceutical services must be such that any person receiving those services does so otherwise than at the proposed premises;
  - 2.2.3 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;
  - 2.2.4 the pharmacy procedures for the premises must be such as to secure:
    - 2.2.4.1 the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and
    - 2.2.4.2 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 you or your staff; and
  - 2.2.5 nothing in your practice leaflet, in your publicity material in respect of the proposed premises, in material published on behalf of you publicising services provided at or from the proposed premises or in any communication (written or oral) from you or your staff to any person seeking the provision of essential services from you must represent, either expressly or impliedly, that:
    - 2.2.5.1 the essential services provided at or from the premises are only available to persons in particular areas of England, or you are likely to refuse, for reasons other than those provided for in your 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 you is limited to other categories of patients).
  - 2.2.6 Enclosed is a form confirming acceptance of these conditions. It should be signed by an authorised person to confirm that you accept the condition imposed by virtue of regulation 64(3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, and returned to me.

The full reasons for the decision are contained in the NHS England South East (Thames Valley) Pharmaceutical Services Regulations Committee Decision which states:

- 2.3 Distance Selling / Maneph Resources Ltd, Office Suite N, First Floor, The Kidlington Centre, High Street, Kidlington, OX5 2DL, Oxfordshire CCG / Oxfordshire HWB
- 2.4 An application from Maneph Resources Ltd for a Distance Selling pharmacy had been received on 12th June 2018. The Committee was now required to consider the application in accordance with Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.

#### CONSIDERATION

- 2.5 The Committee considered the following:

- 2.5.1 The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended;
  - 2.5.2 Department of Health guidance on Distance Selling Premises;
  - 2.5.3 The application form provided by the applicant;
  - 2.5.4 Representations made by Sutton Chase Ltd, Thames Valley LPC and Lloyds Pharmacy Ltd;
  - 2.5.5 The applicant's response to the representations received during the consultation period and the additional information provided;
  - 2.5.6 The Committee decided it was not necessary to hold an oral hearing before determining the application;
  - 2.5.7 A map of the locality showing the nearest community pharmacies and GP Surgeries, in relation to the proposed premises for the Distance Selling pharmacy;
  - 2.5.8 The Committee took into account statements made by the applicant as to the provision of Essential services without public contact. The applicant had stated that: "our pharmacy is situated on an upper floor of an office building and there will be no signage so as to minimise the chances of inadvertent face to face contact. Moreover, there is no shop front which might inadvertently encourage such communication.";
- 2.6 Regulation 31 – the committee was satisfied there is no pharmacy providing pharmaceutical services at the same or adjacent premises. The application did not therefore need to be refused in accordance with Regulation 31.
  - 2.7 The applicant stated on the application form that it intends to provide some advanced services (NMS).
  - 2.8 The Committee noted that the pharmacy intends to open for 40 core hours per week.
  - 2.9 In its consideration of the reasons supplied by the applicant as to why the application should not be refused, the Committee noted that the applicant had detailed how they would comply with all essential services and gave details of how they provide support for self-care.

## DECISION

- 2.10 Having considered the application, representations received and all additional information, the Committee determined to approve the application.

## REASONS FOR DECISION

- 2.11 The reasons for this decision are as follows:
- 2.12 Regulation 25(1)
  - 2.12.1 The committee noted that as this was a distance selling application Regulation 25(1) indicates that section 129(2A) of the National Health Service Act 2006 does not apply, provided that Regulation 25(2) does not require the application to be refused.
- 2.13 Regulation 25(2)(a)

- 2.13.1 The Committee noted the proposed address and that it is not in the same site or building as a provider of primary medical services with a patient list. The Committee therefore did not have to refuse the application under Regulation 25(2)(a)
- 2.14 Regulation 25(2)(b)
- 2.14.1 The Committee noted that it had to be satisfied that services would be provided on an uninterrupted basis to patients anywhere in England and that essential services would be provided safely and effectively without face to face contact
- 2.14.2 The Committee was satisfied that there would be uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services as the opening hours stated and the details of the staffing provided did not allow for any breaks for the pharmacist.
- 2.14.3 The Committee took the view that where compliance with the Terms of Service would ordinarily require face to face contact, the applicant must explain how it is going to achieve compliance (and therefore safe and effective provision) without the face to face contact
- 2.14.4 The Committee considered Schedule 4 to the Regulations having regard to the additional information supplied by the applicant in support of the application.
- 2.14.5 Schedule 4, paragraph 7 – the Committee considered whether the Applicant had explained how evidence would be sought and provided about the patient’s entitlement to exemption from NHS Charges. The Committee noted the applicant’s comments on the application form: “When patient’s sign up to our service they will be asked to tick their exemption on the form. The patients will then be asked to send a picture of their exemptions cards and send via secure email, WhatsApp, fax or Freepost envelopes.”
- 2.14.6 The Committee was satisfied that paragraph 7 would be complied with effectively.
- 2.14.7 Schedule 4, paragraph 8 – the Committee noted that the applicant intended to provide appliances under Part IX of the Drug tariff except for those appliances requiring measurement or fitting.
- 2.14.8 Schedule 4, paragraph 14 - The Committee considered whether the applicant had explained how it would accept unwanted drugs from patients. The Committee noted the applicant’s comments, indicating that “On client demand, we will nationally via our courier offer to collect and safely dispose of any unwanted appliances and medicines in a manner that an audit trail is kept. DOOP bins will be in our office to store waste in time for the waste disposal contractor. Returned medicines will be stored separately.”
- 2.14.9 The Committee took into account the other comments made by the applicant and concluded that on balance, it was satisfied that the requirement of paragraph 14 would be complied with safely and effectively.
- 2.14.10 Schedule 4, paragraph 16 – The Committee considered the applicant had explained how it would promote public health messages to members of the public. The committee considered it had been provided with sufficient information and was satisfied that paragraph 16 would be complied with safely and effectively

2.14.11 Schedule 4, paragraph 19 - The Committee concluded the Applicant had not demonstrated how it would assess patients' need before signposting them in order to minimise inappropriate use of health or social care services.

2.14.12 Schedule 4, paragraph 21 – The Committee concluded the Applicant had not demonstrated how it would provide advice or support for people caring for themselves or their families

2.14.13 Schedule 4, paragraph 28 - The Committee concluded the Applicant had not demonstrated how it would comply with all components of clinical governance.

2.15 For the reasons above, the Committee concluded that the application should be approved

### THIRD PARTY RIGHTS OF APPEAL

2.16 The Committee decided that the parties that should have the right to appeal the decision of NHS England are:

2.16.1 Sutton Chase Ltd

## 3 The Appeal

Using the on line form for pharmacy application appeals dated 6 November 2018, Sutton Chase Ltd (t/a Parade Pharmacy) appealed against NHS England's decision. The grounds of appeal are:

3.1 In an application dated 12 June 2018, Maneph Resources Ltd applied for a distance selling pharmacy at the above address. Sutton Chase Ltd responded on 9 July 2018 and pointed out the following:

*"The onus is on the applicant to demonstrate that they can satisfy the NHSCB that the pharmacy procedures are likely to secure the uninterrupted provision of essential services to persons anywhere in England. The applicant has not done this. By using vague and off-the-shelf SOPs the level of detail is not there to assure the NHSCB that the Regulations will be met. For example, the applicant has mentioned on page 10 about deliveries and that "our contract is for same day or next day deliveries". No copy of the contract has been provided nor other details such as who the contract is with and whether their logistics agents are audited for being able to safely, securely and promptly deliver controlled drugs and refrigerated medicines to anywhere in England. The applicant already has a pharmacy located near to the site of this application and makes no mention whether they will use their own drivers for local deliveries.*

*Sutton Chase Ltd recommend that the superintendent of Maneph Resources Ltd should be personally interviewed in order to determine how the premises will be secured against public access, whether the SOPs accurately reflect the actual practice that will be followed for deliveries and whether they can assure the NHSCB how the uninterrupted supply of all essential services to anyone anywhere in England will be provided. Sutton Chase Ltd therefore propose that under Regulation 25 an oral hearing should be held and Sutton Chase Ltd would like to be invited to give evidence."*

3.2 On 8 October 2018, NHS England communicated their decision and correctly stated:

*"...Schedule 4, paragraph 19 - The Committee concluded the Applicant had not demonstrated how it would assess patients' need before signposting them in order to minimise inappropriate use of health or social care services.*

*Schedule 4, paragraph 21 – The Committee concluded the Applicant had not demonstrated how it would provide advice or support for people caring for themselves or their families*

*Schedule 4, paragraph 28 - The Committee concluded the Applicant had not demonstrated how it would comply with all components of clinical governance."*

- 3.3 Despite NHS England stating that the applicant had NOT demonstrated how they would meet the requirements of paragraphs 19, 21 and 28 they then went on to state:

*"For the reasons above, the Committee concluded that the application should be approved"*

- 3.4 It appears that NHS England has correctly decided that the application is lacking in the necessary detail required and that the applicant had not assured them that they would meet the requirements of the Regulations. This should have resulted in the application being refused and it appears that NHS England have made a mistake in granting the application.

- 3.5 Sutton Chase Ltd therefore respectfully request that NHS Resolution, correct the error of the NHSCB and refuse this application. Should an oral hearing be held, Sutton Chase Ltd would be delighted to attend.

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

This is a summary of representations received on the appeal.

##### 4.1 MANEPH RESOURCES LTD

###### 4.1.1 Matters to be considered

###### Regulation 31

- 4.1.2 The Applicant avers that refusal of the application under Regulation 31 does not apply as the proposed premises does not fall under the provisions of said regulation.

###### Regulation 25

- 4.1.3 The Applicant disagrees with the conclusion reached by NHS CB in determining the application stating inter alia:

*" ... Schedule 4, paragraph 19 - The Committee concluded the Applicant had not demonstrated how it would assess patients' need before signposting them in order to minimise inappropriate use of health or social care services.*

*Schedule 4, paragraph 21- The Committee concluded the Applicant had not demonstrated how it would provide advice or support for people caring for themselves or their families*

*Schedule 4, paragraph 28- The Committee concluded the Applicant had not demonstrated how it would comply with all components of clinical governance. "*

- 4.1.4 In reaching these conclusions NHSCB did not take account of Section 22 of the draft SOP submitted (already in your possession) and the 14 page summary document submitted by email on Tuesday August 14, 2018 (and receipt acknowledged by email of Thursday 16 August, 2018). The latter

document (copy attached for convenience) addresses those issues on the following pages:

- 4.1.5 Sign posting- Page 11
- 4.1.6 Advice & Support- Pages 10 & 12
- 4.1.7 Clinical Governance -Page 12

Appeal on behalf of Sutton Chase Ltd

- 4.1.8 The appellant accept that they made assumptions about the application but appear to transmute those assumptions into fact despite documentary evidence to the contrary (draft SOPs, and the summary document).
- 4.1.9 The appellant also made recommendations such as a personal interview, and demands to relating to the contract(s) with couriers/vendors as well as deployment of the personnel (delivery driver). The appellant does not indicate the Regulatory basis for these recommendations and/or demands, and consequently fails to demonstrate the merit of the appeal.

Re-determination of the Application

- 4.1.10 For the purposes of re-determining this application, the Applicant wishes to reiterate NHS England's national policy document, "Policy for monitoring compliance with the terms of service for pharmacy and dispensing appliance contractors" (5 April 2013) contains a section on SOPs that states:

*2.11 "The essential service and clinical governance specifications require pharmacies to have appropriate standard operating procedures/or dispensing, repeat dispensing and support for self- care. Monitoring compliance requires only the determination (Whether the pharmacy has an appropriate SOP. It does not require NHS England to carry out a detailed analysis of the content of the SOPs. Indeed, it would be unwise for an NHS England employee to carry out any detailed examination because he or she will be unable to determine what is appropriate for the individual pharmacy concerned. Any shortcomings not identified, or suggestions made which themselves cause problems in delivery of the services could lead to NHS England itself being involved in litigation."*

- 4.1.11 The Applicant submitted draft SOPs and supplementary documents together with their application and in section 7 of the application form clearly stated that they were providing 'some relevant SOPs' and that 'details are in the full suite of SOPs'.
- 4.1.12 The Applicant provided the draft SOPs and the supplementary documents as an indication that they wished their application to be judged on the procedures contained therein, and their practice to be monitored by those standards.
- 4.1.13 Nevertheless to enable NHSCB (and now NHS Resolution) to satisfy itself on the merit of the application, the Applicant provides the additional summary (referred to above and attached for convenience) from the Policies and Procedures which gave additional detail but leaving out elements which the Applicant does not think relevant and commercially sensitive material.

Additional Information in Relation to Provision of Essential Services in compliance with Regulatory Requirements for Distance Selling Pharmacies.

- 4.1.14 Please find below ADDITIONAL 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.

#### GPhC Guidance

4.1.15 To ensure safe and effective operations, the Applicant will operate the pharmacy in accordance with the "Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet" issued in April 2015.

#### GPhC Registration of the Premises

4.1.16 The premises will be registered with the GPhC prior to entry to the pharmaceutical list and will therefore comply with GPhC requirements for pharmacy premises.

#### Risk Assessment

4.1.17 Before commencement of operations the Applicant undertake a Risk Assessment exercises.

4.1.18 the Applicant will use a Risk Assessment document and risk matrix to help identify and manage risks, looking at what could cause harm to patients and people who use the pharmacy services, and what the pharmacy needs to do to minimise risk. The risk assessment will include consideration of;

4.1.18.1 how staff tell patients and the public about the pharmacy services they will receive, and how they obtain patient consent;

4.1.18.2 medicines supply, including counselling and delivery;

4.1.18.3 the Applicant's capacity to provide the proposed services, and

4.1.18.4 business continuity plans, including website and data security

4.1.19 The risk assessment will be reviewed periodically and also when there are operational changes.

#### Audit

4.1.20 A regular audit programme will be in place to provide evidence and assurance that the pharmacy continues to provide safe pharmacy services to patients. Any issues identified will be subject to a post audit review as part of the audit cycle.

4.1.21 The audit will examine;

4.1.21.1 Staffing levels, training needs and skills mix within the team

4.1.21.2 Suitability of communication methods with patients, and between staff and other health care providers, including between hubs and spokes and with collection and delivery points (if applicable)

4.1.21.3 Use of specialised equipment and new technology

- 4.1.21.4 Systems and processes for receiving prescriptions, including EPS records of decisions to make or refuse a sale (the pharmacy SOPs may require more frequent evaluation of refusals to sell)
- 4.1.21.5 Systems and processes for secure delivery to patients
- 4.1.21.6 Information about pharmacy services publicly available on the website
- 4.1.21.7 Review of compliance with information security policy, Payment Card Industry Data Security Standard (PCI DSS) and data protection law
- 4.1.21.8 Patient and customer feedback complaints, concerns and compliments
- 4.1.21.9 Activities of third parties, agents or contractors, e.g. courier services etc.
- 4.1.21.10 The Audit result will form the basis of the Business plan for the pharmacy to implement change and upgrades in service and training.

#### Post Audit Review

- 4.1.22 A reactive review will take place post audit if
  - 4.1.22.1 an audit identifies a problem,
  - 4.1.22.2 or if any of the following changes;
  - 4.1.22.3 the law affecting any part of the pharmacy service
    - 4.1.22.3.1 a significant change in the pharmacy service provided, for example an increase in the number of patients or range of services
    - 4.1.22.3.2 the technology the pharmacy uses
  - 4.1.22.4 a data security breach occurs
  - 4.1.22.5 valid concerns or justified negative feedback from patients and/or customers are raised
  - 4.1.22.6 a review of near misses and error logs causes a concern
- 4.1.23 Responsible Pharmacist and Working Time Directive
- 4.1.24 During opening hours there will always be a responsible pharmacist (RP) on site. Each area of work will have clear lines of accountability that will be set out in the SOPs.
- 4.1.25 Any breaks in working time taken by the Responsible Pharmacist will be covered by a second pharmacist who then becomes the Responsible Pharmacist.

#### Record Keeping

- 4.1.26 Records in the pharmacy will be scanned in to the pharmacy IT system (including but not limited to, patient consent forms, queries, complaints, customer logs, sale refusals, and dispensing). Records will be kept for a minimum period of 7 years or longer if specific legislation requires.

#### Website

- 4.1.27 The pharmacy will operate a single website through which P medicines will be sold. The website will be secure and follow information security management guidelines and the law on data protection.
- 4.1.28 The website will use secure facilities for collecting, using and storing patient details and a secure link for processing card payments. The website will display;
- 4.1.28.1 the GPhC pharmacy registration number
  - 4.1.28.2 the name of the owner of the registered pharmacy
  - 4.1.28.3 the name of the superintendent pharmacist
  - 4.1.28.4 the name and address of the registered pharmacy that supplies the medicines
  - 4.1.28.5 details of the registered pharmacy where medicines are prepared, assembled, dispensed and labelled for individual patients against prescriptions (if any of these happen at a different pharmacy from that supplying the medicines)
  - 4.1.28.6 information about how to check the registration status of the pharmacy and the superintendent pharmacist
  - 4.1.28.7 details of specific services available and how to use them, e.g., Return of unwanted medicines, sign posting, public health campaigns etc.
  - 4.1.28.8 Patient Lifestyle Questionnaire
  - 4.1.28.9 How to register exemptions from NHS charges
  - 4.1.28.10 Promotion of Health lifestyles and details of campaigns being undertaken
  - 4.1.28.11 Procedures for Emergency Supply
  - 4.1.28.12 Explanation of rules on non face to face contact
  - 4.1.28.13 Annual patient survey and reports thereof
  - 4.1.28.14 Patient Information leaflet
  - 4.1.28.15 Contact details e.g. the email address and phone number, skype contact, WhatsApp contact etc. of the pharmacy
  - 4.1.28.16 Details of how patients and users of pharmacy services can give feedback and raise concerns
  - 4.1.28.17 GPhC internet logo (linked to register entry)

## MHRA

- 4.1.29 The pharmacy will be registered with the Medicines and Healthcare products Regulatory Agency (MHRA) and to be on the MHRA's list of UK registered online retail sellers.

## EU common logo

- 4.1.30 The pharmacy will display the new EU common logo on every page of the website offering medicines for sale, even if they are already displaying the GPhC voluntary logo. The registered EU common logo will also be linked to the entry in the MHRA's list of registered online sellers.

## Patient Consent

- 4.1.31 Patients will be asked to provide informed consent for any pharmacy services that the pharmacy provides to them. Patient consent forms for services will be stored as part of the PMR record created for all patients that use the pharmacy services.

## Managing Medicines Safely

- 4.1.32 The pharmacy SOPs provide the procedures for all staff to follow to ensure that the sale and supply of medicines is done in such a manner as to minimise risk to patients. The supply or sale of any new medicine must be approved by the Responsible Pharmacist and/or the Superintendent Pharmacist as suitable for sale via distance selling.

## Supplying Medicines Safely

- 4.1.33 The SOPs for delivery of medicines contain detailed information on the safe and effective supply of medicines via potential options including the pharmacy's own driver, Royal Mail and contracted courier firms. The detailed SOP covers aspects including;
  - 4.1.33.1 assessing the suitability and timescale of the method of supply, dispatch, and delivery for all medicines and particularly refrigerated medicines and controlled drugs
  - 4.1.33.2 assess the suitability of packaging (for example, packaging that is tamperproof or temperature controlled)
- 4.1.34 Prior to concluding the contract (under negotiation) with the carrier the pharmacy will check the terms, conditions and restrictions of the carrier.
- 4.1.35 The pharmacy will monitor third-party providers, including analysis of patient feedback about deliveries and delivery times and processes.

## Equipment and Facilities

- 4.1.36 All equipment used in the pharmacy will be sourced from manufacturers that have designed the equipment to be used in the manner in which the pharmacy intends to operate.
- 4.1.37 All equipment will be subject to annual performance testing and review, with specialist equipment (such as temperature monitoring) subject to monthly checks.

- 4.1.38 IT equipment will meet the latest security specifications and be regularly updated including the use of encrypted networks for wired and wireless communication. Access to records will be dependent on any given employee's level of authority and clearance which shall be determined by the superintendent pharmacist.

#### Standard Operating Procedures

- 4.1.39 the Applicant has already developed a draft suite of operating procedures to cover all aspects of the operations of this distance selling contract. If NHS England requires any further information about any aspect of the operation of the pharmacy then the relevant SOP will be provided upon request.
- 4.1.40 the Applicant has not provided all draft SOPs with this application as they contain commercially sensitive material.

#### Pharmacy Systems and Procedures

- 4.1.41 All Essential Services will be delivered in accordance with:

4.1.41.1 Standard Operating Procedures

4.1.41.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

4.1.41.3 NHS Act 2006

4.1.41.4 Human Medicines Regulations 2012

4.1.41.5 RPSGB- Professional Standards and Guidance for Internet Pharmacy Services

4.1.41.6 PSNC- Guidance on Internet Selling Pharmacies

4.1.41.7 GPhC- Professional Standards and Guidance on Distance Selling Pharmacies

- 4.1.42 These are to ensure that the pharmacy provides safe, effective and uninterrupted provision of all essential services to persons anywhere in England who request those services during the opening hours of the premises. Essential Services will be provided without face to face contact between anyone receiving the services, whether on their own or someone else's behalf, and the pharmacy staff.

#### NHS Services

- 4.1.43 Access to information about the provision of NHS Essential Services will be achieved by using:

4.1.44 Telephone

4.1.44.1 The website will enable patients or their carers to communicate remotely but directly allowing quick and easy access and provide clear unambiguous details of how safe, efficient, uninterrupted NHS Essential Services will be provided by the Pharmacist and qualified, knowledgeable, experienced support staff on duty throughout the opening hours of the pharmacy premises without having 'face to face' contact with the patient or their representative.

4.1.45 Email

4.1.46 Courier & Postal services

4.1.46.1 All NHS services will be delivered free of charge in accordance with the NHS Act 2006.

4.1.47 Essential Services will be delivered by using:

4.1.47.1 Telephone, including text messaging where appropriate

4.1.47.2 Electronic Prescription Service (EPS)

4.1.47.3 Website

4.1.47.4 Email

4.1.47.5 Royal Mail postal service

4.1.47.6 Courier service

4.1.47.7 Specialist Waste Management Services

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

#### Provision of NHS Essential Services

4.1.48 The pharmacy will provide all the Essential Services as outlined in the NHS contractual framework.

4.1.49 Dispensing Services

4.1.49.1 Prescriptions will be received by the EPS, post, and fax or where practicable, with the patient's informed consent, collected from a surgery. Prescriptions will be clinically and legally assessed to determine if they can be dispensed.

4.1.49.2 In the event that they are not clinically or legally correct, pharmacists will follow Standing Operating Procedures to resolve clinical or legal issues before dispensing items. This may involve contacting the prescriber as soon as possible to make sure the patient receives their medication without delay.

4.1.49.3 When appropriate prescription interventions will take place for example drug/drug interactions, suspected over/under prescribing, etc. The pharmacist on duty will telephone and discuss with the Prescriber prior to dispensing or delivering the medication.

4.1.50 Repeat Dispensing Services

4.1.50.1 The March 2015 Terms of Service require the Pharmacy to ensure that 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, including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on.

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

4.1.51 Dispensing of repeat NHS prescriptions including those dispensed in dosette boxes as may be required under the Disability Discrimination Act will be done in partnership with patients, carers, pharmacists and prescribers. It will cover requirements additional to those for dispensing, assessing the patients' need for repeat supply. Any clinical issues identified will be addressed to the prescriber.

4.1.52 Where considered necessary by a pharmacist, the patient may be contacted by telephone and given verbal advice in addition to information delivered with the repeat prescription.

#### Delivering Medicines

4.1.53 The Responsible Pharmacist (RP) has overall responsibility for ensuring the delivery of medicines to intended patients. Medicines must be delivered safely and with appropriate instructions.

4.1.54 The RP must take adequate measures to ensure that the delivery mechanism used is secure and that medicines are delivered to the intended user promptly, safely, and in a condition appropriate for use. If the delivery to patients is local, this will be done by the delivery driver. All other nationwide delivery will be delivered by special delivery and signed for by the patient, their notified carer or other patient authorised representative.

4.1.55 The patient will be provided with a tracking number to track the status of the delivery online. A text messaging system will inform the patient about their delivery.

4.1.56 Medicines will be packed, transported and delivered in such a way that their integrity, quality and effectiveness are preserved. The delivery mechanism used will provide a verifiable audit trail for medicine from the initial request through to its final delivery, or its return to the pharmacy in the event of a delivery failure. Packaging must maintain patient privacy and confidentiality.

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

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

4.1.59 Medicines classified as non-flammable or non-toxic must be securely closed and placed in a leak proof container such as a sealed polythene bag (for liquids) or a sift proof container (for solids). Must be tightly packed in strong outer packaging and must be secured or cushioned to prevent any damage.

- 4.1.60 This means that for postal /courier items, either:
- 4.1.60.1 At the very least- padded envelopes even for non-fragile items as this will help to ensure the integrity of the manufacturers packaging.
  - 4.1.60.2 For most items- bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. Cardboard boxes must be the re-enforced type.
  - 4.1.60.3 Large or any fragile medicines should be packed into cardboard boxes with bubble packaging and filling material to protect from damage.
- 4.1.61 The patient, carer or notified, authorised patient representative must always sign and date a receipt to prove safe receipt of the medicines. A patient who is not at home when delivery is attempted will be informed using a non-delivery notice and an alternative delivery date will be arranged.

#### Cold Chain Couriers

- 4.1.62 A list of the approved cold chain couriers is available within the Pharmacy. Cold chain items should be stored in Styrofoam filled cardboard boxes prior to being passed to the courier and marked with the "FRAGILE" and "FRIDGE LINE" stickers. Additional packing will not be required as the courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box and are fully monitored. Pharmacy staff should be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in: medicines which is damaging to them. The courier service is a dedicated, fully monitored and temperature controlled delivery service. Any breach of the cold chain is automatically notified to the driver who will then follow the failed delivery procedure and notify the pharmacy accordingly so that re-delivery can be arranged. Where the cold chain breach notice is issued items may not be re-used.

#### Delivery of Controlled Drugs

- 4.1.63 Controlled drugs legislation provides cover for occasions when a controlled drug (CD) may temporarily be in the possession of a third party, e.g. a delivery person or postal carrier, while it is being transferred from one authorised person to another authorised person who is entitled to be in possession of the drug. Delivery of CD will be carried out by couriers with pharma grade specialist facilities to meet specific quality and validation requirements for health care products. This includes Home Office licensed controlled drug stores. The couriers will have the following UK Licenses and Standards:
- 4.1.63.1 MHRA Wholesale Dealer License
  - 4.1.63.2 MHRA Manufacturers Importers License
  - 4.1.63.3 MHRA IMP License
  - 4.1.63.4 ISO 9001: 2000 Certified
  - 4.1.63.5 Meet all Home Office safe custody and record keeping requirements Return and Destruction of CD
- 4.1.64 Patients wishing to return CDs to the pharmacy may do so by making an appointment in advance with the pharmacy. Appropriate packaging will be

sent to patients in advance with instructions for packaging any returned medicines and this will be provided and paid for by the pharmacy. The Superintendent Pharmacist will specify the appropriate method of collection depending on the items being returned and the distance from the pharmacy. Patients may also be sign posted to alternate pharmacies if they prefer to return medicines to a different pharmacy. Any 'returned' Controlled Drugs must not be re-used or entered into the CD register. The Pharmacy will denature and render them irretrievable as soon as possible in order to avoid storage problems and an increased security risk.

- 4.1.65 Destruction must be witnessed by another member of staff. If not immediately destroyed, they should be segregated from main stock, clearly marked 'Patient Returns' to minimise the risk of errors and inadvertent supply and stored securely in a CD Cabinet waiting to be denatured. A record of destruction will be recorded in a separate CD Destruction Register designated for this purpose and will be available in the pharmacy for inspection.

#### Urgent Supply

- 4.1.66 Whilst the Distance Selling nature of the pharmacy is such that Emergency Supply is likely to be rare, all staff will be aware of the procedures to be followed in the event of such a request. The request may be received from a Prescriber (check list of Prescribers e.g. from the GMC website, EEA prescribers cannot request an emergency supply of any Schedule 1- 5 CD) or from a Patient The following conditions must apply to the request made by a prescriber:

4.1.66.1 The Pharmacist must be satisfied that the request is from the appropriate authorised prescriber, see list above.

4.1.66.2 The Pharmacist is satisfied that a prescription cannot be supplied immediately due to an emergency.

4.1.66.3 The Prescriber agrees to provide a written prescription within 72 hours.

4.1.66.4 The medication is supplied in accordance with the prescriber's directions.

4.1.66.5 The medication is 'legally permitted to be supplied on an Emergency Supply basis, e.g.: an emergency supply cannot be provided for a Schedule 1, 2 or 3 CD except Phenobarbital for epilepsy by a UK registered prescriber. Full records of the supply will be kept as per the relevant SOP.

#### Patient Request

- 4.1.67 The Pharmacist must interview the patient to establish the appropriateness as well as the consequences of supplying or not. The interview must not be by way of face to face contact and must be by other means, e.g., telephone, Skype, video call, WhatsApp call, etc. Records- must be made in the POM register on the day of supply and record all the relevant details.

- 4.1.68 Label- the label for the dispensed medicine must contain the words "Emergency Supply".

#### Faxed Prescriptions

- 4.1.69 According to RPS guidance, a 'faxed prescription' does not fall within the definition of a legally valid prescription because it is not written in indelible ink, and has not been signed by an appropriate practitioner. A faxed prescription can confirm that at the time of receipt a valid prescription is in existence.
- 4.1.70 Any pharmacist who decides to dispense a prescription only medicine against a faxed prescription without sight of the original prescription must ensure that adequate safeguards exist to ensure that the original prescription will be in their possession within a short period and not more than 72 hours.
- 4.1.71 Any doubt as to the content of the original prescription caused by poor reproduction must be overcome before the medicine is supplied by contacting the prescriber.
- 4.1.72 Other than in emergency situations it is recommended that the pharmacist does not dispense against faxed prescriptions and instead uses the Emergency Supply procedures.
- 4.1.73 As it is possible to fax a prescription many times the pharmacist is advised to ensure that no dispensing against a fax takes place unless the system used for the sending or receipt of faxes is secure.
- 4.1.74 Schedule 1, 2, or 3 CDs (except Phenobarbital for the treatment of epilepsy) must not be supplied against a faxed prescription.
- 4.1.75 As detailed above the patient should be interviewed over the phone. Payment can be processed via the website or over the phone. The pharmacist may wish to consider the following before providing an emergency supply at the request of the patient:

#### Delivery of Urgent Supplies

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

#### Disposal of Unwanted Medicines

- 4.1.77 Specialist Waste Management Services company must be appointed as required from time to time to provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.
- 4.1.78 Upon return to the pharmacy unwanted medicines will be sorted and placed in disposal units ready for waste management services to collect. The disposal service will be advertised on the website/app and marketing leaflets.
- 4.1.79 Patients wishing to return unwanted medicines to the pharmacy may do so by courier, which will be provided and paid for by the pharmacy. Patients in locality may contact pharmacy by phone or email to arrange collection of unwanted medicines from their home or work by pharmacy staff.

- 4.1.80 Appropriate packaging will be sent to patients in advance and details of the service and how to book a collection will be available on the Pharmacy website.

#### Public Health (Promotion of Healthy Lifestyles)

- 4.1.81 Identification of patients for promotion of healthy lifestyles can be either opportunistic or active. Active patients will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further.
- 4.1.82 information should be sent, or who should be called to follow up on the results and offer additional support and information.
- 4.1.83 Opportunistic identification happens as part of another interaction with the patient, but where the patient may not overtly be seeking additional assistance. For example, the dispensing of a prescription which identifies the patient as having high blood pressure.
- 4.1.84 All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.
- 4.1.85 Leaflets will be delivered to patients with their medication. Those identified (Active or Passive) as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles.

#### Public Health Campaigns

- 4.1.86 The Pharmacy will take part in national health campaigns to promote public health messages to our patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website.
- 4.1.87 Patients will be directed to the learning resources via email, text and other non face- to-face communication so that they are aware of the campaign.
- 4.1.88 From 1 March 2015 patients should also be assessed for participation in at least one clinical audit and whichever of the following that the NHSCB specifies-
- (i) a clinical audit carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit, or
  - (ii) a policy based audit (to support the development of the commissioning policies of the NHSCB) carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit.

#### Sign posting

- 4.1.89 The Pharmacy will signpost and continually undertake assessment of whether patients require advice to minimise inappropriate use of health or social care services.
- 4.1.90 Any help or advice that cannot be accessed on the website and app links will be available by telephoning the pharmacy and asking for advice. The patient will then be sign posted to health and social care providers and/or any other assistance available. To assess whether patients require advice to minimise inappropriate use of health or social care services the pharmacist will use the same "Active and Opportunistic" assessment tool already set out above.
- 4.1.91 Where it appears to the pharmacist, after reviewing the assessment and having regard to the need to minimise inappropriate use of health and social care services and of support services, that a person using the pharmacy-
- (a) requires advice, treatment or support that the pharmacy cannot provide; but
- (b) another provider, of which the pharmacy is aware, of health or social care services or of support services is likely to be able to provide that advice, treatment or support,
- 4.1.92 The pharmacy will provide contact details of that provider to that person and will, in appropriate cases, refer that person to that provider.
- 4.1.93 Where, on presentation of a prescription form or repeatable prescription, the pharmacy is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within the pharmacy's normal course of business, the pharmacist will-
- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the pharmacist.
- (3) Where appropriate, a referral can be made by means of a written referral note.
- (4) In appropriate cases, the pharmacist will keep and maintain a record of any information given or referral made to facilitate auditing and follow up care.

#### Support for Self-Care

- 4.1.94 Information about support organisations, the treatment of common illnesses, minor ailments, long term medical conditions and appropriate usage of OTC medications will be available on the website, app and email newsletter. The pharmacist on duty can be contacted by telephone for more advice and drug interactions.
- 4.1.95 There will also be pharmacist selected web links and 'downloads' to print off.

#### Support for People with Disabilities

- 4.1.96 This service will be provided in accordance with the Disability Discrimination Act (DDA). The Pharmacy will make reasonable pharmaceutical adjustment to ensure that those who qualify for help under the DDA are provided with the right compliance aids.
- 4.1.97 The Pharmacy will conduct an initial assessment with the patient, care or representative to assess the support required to improve medication compliance. Such assessments will be carried out without patients having to access the pharmacy premises, so that no face-to-face contact at the premises will take place.
- 4.1.98 Compliance aid systems such as blister packs/dosette boxes will be provided in compliance with both service levels 1 & 2 respectively.

#### Clinical Governance

- 4.1.99 Clinical Governance is not an 'essential service' and is therefore only dealt with briefly in this submission.
- 4.1.100 The Pharmacy will be involved in and comply with all the components of clinical governance including, but not limited to, compliance with standard operating procedures, patient safety incident and near miss reporting, demonstrating evidence of Pharmacists and Pharmacy Technician CPO, conducting clinical audits and patient satisfaction surveys, and drug recalls.
- 4.1.101 'How to Make a Complaint or compliment' will be displayed and downloadable from the pharmacy website or upon request by telephone or post a copy will be posted.
- 4.1.102 All staff will be qualified or undergoing nationally accredited training. They will be competent to deliver the highest standards of Clinical Governance. All staff will receive individual and collective training, development and education provided in- house or from accredited external providers.
- 4.1.103 All staff will have an annual appraisal, receive and provide feedback.
- 4.1.104 The Pharmacy will conduct an annual PSS based on the template recommended by the PSNC.
- 4.1.105 Details of the survey (as per PSNC website) can be found at <http://psnc.org.uk/contractit/essentialservice-clinical-overnancelcppql>
- 4.1.106 The survey will be adapted to reflect the operation of a distance selling pharmacy, ie
  - 4.1.106.1 Distributed via email, post and with delivery drivers I couriers
  - 4.1.106.2 References to "visiting" the pharmacy changes to reflect non face to face contact methods used.
  - 4.1.106.3 Ratings for the pharmacy based on physical characteristics changed to reflect actual method of use, ie ease of use of website as opposed to "comfort and convenience of the waiting areas".

#### Information Governance

- 4.1.107 The pharmacy will be registered and comply with Data Protection Act. It will also comply with the Access to Health Records Act. It will publish its Freedom of Information Act Publication Scheme on its website and copies

will be made available on request. All patient data will be kept private and confidential in accordance with NHS and legal obligations on data security, protection and confidentiality.

#### Contingency Planning

- 4.1.108 The pharmacy will have accounts direct to pharmacy manufacturers and many full-line and short-line pharmaceutical wholesalers to broaden stock availability
- 4.1.109 A Contingency Plan will be in place to ameliorate the effects of any disruption to provision of pharmaceutical services such as medicines shortage, postal strike, EPS systems failure, etc.

#### Verification of Declarations of Prescription Exemptions

- 4.1.110 The reverse of the prescription should be fully completed (other than age exempt patients) in black ink.
- 4.1.111 The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (ie for deliveries made other than by the pharmacy's delivery driver), the patient may scan or fax copies of the evidence to the pharmacy (or use the postal courier service, but see NOTE below) and the pharmacy can note that the evidence provided was not in original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box.
- 4.1.112 The type of exemption and date of expiry will be recorded in their Patient Medication Record. If they are not exempted prescription charge payments will be made using a secure on-line payment method.
- 4.1.113 Exemptions may be sent to the pharmacy by post and the pharmacy will pay for postage and return the exemption to the patient free of charge. Faxed and scanned email copies of exemptions are also acceptable. The nature of any exemption will be recorded on the PMR system with a copy attached to the patient's file.
- 4.1.114 Payment for prescription charges will be received via the secure payment portal on the website (e.g. PayPal, Sagepay) and when payment is received the prescription will be marked as paid.

#### Practice leaflet

- 4.1.115 Nothing in the pharmacy's practice leaflet, or publicity material in respect of the listed chemist premises, in material published on behalf of the pharmacy publicising services provided at or from the listed chemist premises or in any communication (written or oral) from the pharmacy or the pharmacy's staff to any person seeking the provision of essential services will represent, either expressly or impliedly, that-
  - (i) the essential services provided at or from the premises are only available to persons in particular areas of England, or
  - (ii) the pharmacy is likely to refuse, for reasons other than those provided for in the pharmacy's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of

essential services from the pharmacy is limited to other categories of patients).

#### 4.2 LLOYDS PHARMACY

- 4.2.1 Lloyds wish to support the comments made in the appeal. The applicant does not provide sufficient evidence with regard to how they would deliver all essential services without face to face contact. Regulation 25 and the conditions set out in Regulation 64 have not been met.
- 4.2.2 Lloyds Pharmacy would be grateful if [Primary Care Appeals] would inform them of the decision in due course.

#### 4.3 PHARMACY THAMES VALLEY (THE LPC)

- 4.3.1 The LPC has no further comments to make on this application or appeal but would wish to be kept informed of any decision and reserves the right to attend any appeal hearing if one is called. The LPC have attached their original comments for completeness.

In a letter to NHS England dated 31 July 2018, the LPC stated:

- 4.3.2 An application for inclusion on the pharmaceutical list for a distance selling/ wholly internet pharmacy must be judged against the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 having particular concern to regulation 25 and 64. The following criteria must be taken into account when an application is considered and the LPC has considered these criteria and has included our comments on them:
- 4.3.3 ***A distance selling pharmacy must not provide Essential services to a person who is present at the pharmacy, or in the vicinity of it. In addition, the pharmacy's SOPs must provide for the Essential services to be provided safely and effectively without face to face contact with any member of staff on the premises.*** The applicant has dealt with this in the application and the location as described would not encourage casual contact by a patient. There appears to be no intention to provide face-to-face services. However, the LPC would expect that NHS England would assure itself of this.
- 4.3.4 ***A distance selling pharmacy may provide Advanced and Enhanced services on the premises, as long as any Essential service which forms part of the Advanced or Enhanced service is not provided to persons present at the premises.*** There is nothing to suggest that this would not be complied with but again the LPC would expect that NHS England would take steps to check this.
- 4.3.5 ***The pharmacy's procedures and SOPs must allow for the uninterrupted provision of Essential services during the opening hours of the pharmacy to anyone in England who requests the service.*** The applicant doesn't explain how any gaps in RP cover e.g. for lunch breaks would be covered. The LPC would expect NHS England to be assured that the staffing structure provides for continuous provision without breaching the pharmacist's right to statutory breaks.
- 4.3.6 ***Nothing in any written or oral communication such as a practice leaflet or any publicity can suggest, either expressly or impliedly, that services will only be available to persons in particular areas of England, or only particular categories of patients will (or will not) be provided for.*** Again, the LPC would ask that NHS England seeks assurances on this matter.

- 4.3.7 The LPC trust their views will be of interest to NHS England and the LPC would ask to be kept informed at all stages in the process.

## 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 The Committee noted the request from the Appellant for there to be an oral hearing. The Committee was of the view that the SOPs as provided by the Applicant are comprehensive, however the Committee would expect to see the name of the applicant's pharmacy on the SOPs which, although not determinative, would have the potential to re-assure parties that the SOPs are owned by the applicant. On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.
- 6.4 The Committee noted, in its decision, NHS England state "NHS has considered the above application and is writing to confirm that it has been granted" and then go on to state "As the application is in respect of distance selling premises ... it has been granted subject to..." and "Enclosed is a form confirming acceptance of these conditions."
- 6.5 The Committee is mindful that it is incorrect to say that any grant which has been made by NHS England (or as described in this case, the "approval" which has been given) can, itself, be subject to any conditions.
- 6.6 The Regulations provide that, if and when a successful Applicant is included in the Pharmaceutical List (in consequence of a grant and the service by it of a notice of commencement), their List entry will be subject to the conditions provided in Regulation 64(3). It is the Pharmaceutical List entry, rather than the grant, which is subject to the conditions in Regulation 64.
- 6.7 The successful Applicant's continued inclusion thereafter may well depend on adherence to the conditions but there is nothing to "meet" at the point of entry. The successful Applicant would simply need to serve the notice of commencement required by paragraph 34(2) of Schedule 2 to the Regulations and should then be included in the Pharmaceutical List.
- 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 the Applicant had not provided any information in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee noted that NHS England were of the view that Regulation 31 does not apply for this application as there is no pharmacy providing pharmaceutical services at the same or adjacent premises. The Committee noted that there was no assertion that the application should be refused under Regulation 31. The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

6.11 On the basis of the information provided to it, the Committee concluded that the premises to which this application relates, or the adjacent premises, are not already occupied by a person on a pharmaceutical list who is providing or has undertaken to provide pharmaceutical services.

6.12 The Committee was not required to refuse the application under the provisions of Regulation 31.

### **Regulation 25**

6.13 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."*

6.14 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.*

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

- 6.15.1 confirm NHS England's decision;
- 6.15.2 quash NHS England's decision and redetermine the application;
- 6.15.3 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)**

6.16 In relation to Regulation 25(1), the Applicant is applying for inclusion in the relevant pharmaceutical list as 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, and paragraph (1)(b) 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)**

6.17 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states "Not Applicable" in response to the question why the application should not be refused pursuant to Regulation 25(2)(a).

The Committee noted that this had not been disputed and that it had not been provided with any information to persuade it otherwise. 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)**

- 6.18 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 extracts from its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.
- 6.19 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.
- 6.20 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.
- 6.21 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.
- 6.22 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.
- 6.23 The Committee noted in the Extract from the SOPs provided by the Applicant to NHS England, SOP 1 'Introduction and Background to SOPs' states that the pharmacy must provide:
- 6.23.1 *"the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services".*
- 6.24 Further, SOP 2 "Procedures for NHS Essential Services" states:
- 6.24.1 *NHS Essential services are provided to all patients living in England, this is made clear on the website and in Practice leaflet.*
- 6.25 The Committee also noted that reference is made throughout the SOPs, the application form and subsequent representations, to the provision of services to all of England. In addition, the Committee noted the references in the SOPs to a delivery driver, the use of Royal Mail as well as the use of couriers.
- 6.26 In its SOP 28 "The Responsible Pharmacist", the Applicant states that:
- 6.26.1 *"As a distance selling pharmacy, we must provide uninterrupted services throughout the opening hours of the pharmacy. For this reason the RP is not allowed to leave the premises in the same way as an RP at a non- Distance*

*Selling pharmacy is allowed (for up to 2 hours per day) unless the second pharmacist is present.*

- 6.27 And goes on to state:
- 6.27.1 *"The pharmacy will have a second pharmacist available during the core and any additional hours that it operates. If, for any reason, the RP is required to leave the premises or wishes to take a break.... then the second pharmacist must sign in as the RP".*
- 6.28 The Committee noted the comments from the Applicant that the pharmacy would be situated in an office block and that there would therefore be no shop front for the pharmacy. The Applicant went on to state that there would be no signage outside the front of the building indicating that there was a pharmacy contained within.
- 6.29 Further, the Committee noted that throughout the SOPs, the Applicant states that essential services will be provided without face to face contact between anyone receiving the services and the pharmacy staff. SOP 1 "Introduction and Background to SOPs" states:
- 6.29.1 *"All staff must be made aware that face to face contact between patients (or their representatives) is prohibited in respect of any and all Essential Services either on or in vicinity of the premises."*
- 6.30 The Committee also noted SOP 2 "Procedure for NHS Essential Services" under 'Communication channels' it states:
- 6.30.1 *All communications regarding NHS Essential Services should be carried out over the telephone unless the customer has specifically requested to communicate via email. Skype or other types of video conferencing are also permissible methods of communication as are text messages or other "electronic" communications (eg Facebook, fax, apps).*
- 6.31 The Committee noted that patients would be able to contact the pharmacy by telephone, through the website as well as by email and postal services.
- 6.32 The Committee was aware that when the pharmacy opens, it will be the responsibility of NHS England, in keeping with Regulation 64, to ensure that services are provided other than with face to face contact.
- 6.33 The Committee was satisfied that the provision of services would be without interruption, would be without face to face contact and would be available to persons anywhere in England. The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.
- 6.34 The Committee considered each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") in turn.
- 6.35 The Committee paid particular attention to the following aspects of the essential services, which it considered were more difficult to provide safely and effectively in a distance selling context:

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

- 6.36 The Committee considered whether the Applicant had explained how non-electronic prescriptions will be presented by the patient and how products will be provided.
- 6.37 From the information contained in the SOPs, prescriptions will be received by the Applicant by EPS and post. In its SOP 5 "Online Order Receipt & Exemption Checking" the Applicant states:

6.37.1 *“Requests to collect and dispense NHS Prescriptions from the surgery or patients household”*

*“Requests to dispense a prescription received in the post”* and

*“Any requests from the “contact us” section of the website”.*

6.38 The Committee also had regard to SOP 15 ‘Order Delivery’ which states under “Choice of Delivery Method”:

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

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

#### **Urgent supply without a prescription**

6.40 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.

6.41 The Committee had regard to SOP 13 entitled ‘Emergency Supply and Urgent Supply’ and noted that the Applicant had described how it would process such a request. The Committee noted the SOPs state that essential services will be delivered by using telephone as well as email among other methods of non face to face communication, and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

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

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

6.43 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.

6.44 The Committee noted SOP 5 ‘Online Order Receipt & Exemption Checking’ and in particular “Exempt NHS Prescriptions” which stated:

6.44.1 *“Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce ‘satisfactory evidence’ to confirm exemption. Where appropriate (i.e. for deliveries made other than by the pharmacy’s delivery driver), the patient may scan or fax copies of the evidence to the pharmacy (or use the postal / courier service, ...) and the pharmacy can note that the evidence provided was not in original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the ‘Evidence not Seen’ box.”*

- 6.45 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.
- 6.46 The Committee considered whether the Applicant had explained how charges will be paid.
- 6.47 SOP 5 “Online Order Receipt & Exemption Checking” under the heading “Paid NHS Prescription” states:
- 6.47.1 *“Check to see if any fees have been paid and if so, was the correct amount paid?”*
- Contact the patient to arrange payment using the secure payments system using the “customer not present” option.*
- If no fees have been paid or there is a discrepancy between fees paid and those due, the patient should be contacted and directed to pay the appropriate fees via the online payment system.”*
- 6.48 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

#### **Providing ordered drugs or appliances**

- 6.49 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).
- 6.50 The Committee noted that SOPs had been provided with representations, SOP 15 ‘Order Delivery’ under the heading “Transfer to the Delivery Driver” states:
- 6.50.1 *“Ensure that any special instructions for the delivery are included within the packaging.*
- Ask the delivery driver to check the details on the delivery sheet correspond to the deliveries.*
- Ensure the delivery driver completes all the sections on the delivery sheet including their name and the date.*
- Ensure that any deliveries for fridge items and CDs are taken out of storage when appropriate.*
- Ensure the delivery driver is notified of any messages for the patient or representative.*
- Make and retain a copy of the delivery sheet until the original had been returned by the delivery driver. The original must be returned to the pharmacy on the same day.*
- Ensure the deliveries are placed in the delivery vehicle and are stored securely and out of sight. The delivery vehicle must be locked at all times when left unattended.”*
- 6.51 The Committee noted SOP 15 ‘Order Delivery’ under the heading “Delivery of a prescription via Royal Mail (Not for Cold chain or CDs)” states:

- 6.51.1 *“Follow preparation for delivery process. The pharmacist should contact any patients for whom there are relevant messages or counselling required.*

.....

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

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

*Confirm details of all prescriptions to be delivered.*

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

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

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

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

- 6.52 The Committee noted SOP 15 ‘Order Delivery’ under the heading “Cold chain delivery via courier” states:

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

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

*Cold chain management uses its own terminology. Several temperature ranges are specified in the relevant literature, the most common being controlled-room temperature or CRT (often defined from 15oC to 25oC), but also cool (from 8oC to 15oC), cold or refrigerated (from 2oC to 8oC), frozen (around -10oC) and cryogenic (around -150oC). There is, however, no general or universal glossary that is commonly accepted by all regulatory agencies. For courier deliveries the Pharmacy will normally be advising the courier that delivery must be in the “cold or refrigerated” category.*

*The Cold Shipping Package is designed for customers that require a refrigerated environment of 2-8°C for their shipments and will be the most commonly used in the pharmacy.*

*The packaging device maintains its exacting “cold ship” temperature requirements and is fully monitored to ensure that any breach is notified to the driver who will then notify the Pharmacy and follow the “failed delivery process”.*

*The courier is accredited with the MHRA for the storage of temperature critical pharmaceuticals & medicines and employ a permanent Responsible Person to ensure compliance with the regulatory requirements. Drivers are*

*GDP trained and the operating procedures have been ISO9001 certified for quality.*

*Fully traceable transport of pharmaceuticals & medicines backed by the latest logistics technology provides consignment tracking, live ETA's and electronic proof of delivery. Temperature data for storage and transit is also recorded.*

...

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

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

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

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

#### **Unsuccessful cold chain delivery via courier**

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

#### **Breach of Integrity of Cold Chain ...**

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

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

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

6.53.1 *A robust audit trail is essential when controlled drugs are involved. The delivery can be made to a person who is not the patient (the patient must have given authorisation for a representative to take receipt of CDs on their behalf). The delivery driver/courier should check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative.*

*A Controlled Drugs Delivery Sheet must also be filled in for CD deliveries in addition to the Delivery Log sheet.*

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

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

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

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

### **Successful Schedule 2 & 3 Delivery**

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

### **Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver**

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

### **Unsuccessful Schedule 2 & 3 Delivery via courier**

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

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

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

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

- 6.54 Based on the information before it, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.
- 6.55 The Committee considered whether the Applicant had explained the arrangements which ensure that, for appliances which require fitting / measuring, a registered pharmacist measures / fits them.
- 6.56 The Committee noted that the Applicant had stated in their original application form that this was "not applicable", however in a subsequent letter to NHS England the Applicant stated that this had been completed erroneously and that they would undertake to provide:
- 6.56.1 "Drug Tariff part IX\* (\*except items that require measuring or fitting."

6.57 In SOP 6 “Pharmaceutical and Legal Assessment” under ‘Items requiring measuring and fitting’ the Applicant states:

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

6.58 In its SOP 22 “Support for Self-Care, Signposting and Health Promotion” under the heading “Items requiring measuring and fitting” the Applicant states:

6.58.1 *“Where a prescription is received for an appliance or stoma appliance customisation or any item that requires measuring or fitting the patient should be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients should be sign posted to at least 2 other providers of the service in their area.”*

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

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

6.61 The Committee noted SOP 14 ‘Bagging-Up’ under the heading “Choice of Packaging” states:

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

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

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

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

*For postal items, either:*

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

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

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

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

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

#### **Refusal to provide drugs or appliances ordered**

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

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

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

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

*They are not suffering any side effects which may suggest they need a review of their medication*

*Their medication regimen has not been changed since the prescriber authorised the repeatable medication*

*There have not been any changes to the patient's health since prescription was authorised*

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

*Any interventions or referrals which are deemed to be clinically significant should be recorded on the Intervention and Referral Form."*

- 6.65 The Committee further noted SOP 31 'Repeat Dispensing' under the heading "Prescription Reception" states:

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

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

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

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

6.67 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.

6.68 The Committee noted SOP 31 'Repeat Dispensing' under the heading "Prescription Reception" it states:

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

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

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

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

6.69 In addition the Committee noted under the heading "Pharmaceutical and Legal Assessment" in SOP 31 it states:

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

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

## **Disposal service in respect of unwanted drugs**

6.71 The Committee considered whether the Applicant had explained how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.

6.72 For the return of controlled drugs, the Committee noted SOP 20 "Controlled Drugs: Collection and Disposal of Patient Returns" and in particular the section ' Patient Returned Medication' which states:

6.72.1 *"This service is available to all patients living in England.*

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

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

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

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

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

- 6.73 The Committee noted that SOP 20 goes on to state, under the heading "Return by Royal Mail":

6.73.1 *The pharmacist must*

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

*Assess the items for suitability for return by Royal Mail*

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

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

*Contact the patient to ensure that the package has been received*

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

- 6.74 The Committee further noted that SOP 20 goes on to state, under the heading 'Handling Patient – Returned CDs from Delivery Driver':

6.74.1 *"Drivers need to:*

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

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

- 6.75 The Committee noted SOP 21 "The Safe and Effective Receipt and Disposal of Medicines" states, under the heading "Process for Patients to Return Medication" it states:

6.75.1 *Patient Returned Medication*

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

*This service is available to all patients living in England.*

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

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

*"Patients may*

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

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

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

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

6.76 The Committee noted that the SOP, under 'Process for accepting patient returns by the Driver', stated:

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

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

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

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

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

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

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

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

6.77 The Committee also noted the SOP went on, under the heading 'Disposal of returned medicines' to state:

6.77.1 *"Specialist Healthcare Waste management Services (or such company as may be appointed) can provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.*

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

6.78 The Committee was of the view that the Applicant expects the patients to follow the instructions provided on its website in order to return unwanted medication so that the pharmacy can arrange such returns.

6.79 Based on all of the information before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 13 - 15 of Schedule 4.

## Promotion of healthy lifestyles

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

6.81 The Committee noted SOP 23 “Promotion of Healthy Lifestyle & Public Health Campaigns” under the heading ‘Public Health Campaigns’ states:

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

...

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

6.82 Further, in SOP 23 under the heading “Identification of patients for promotion of Healthy Lifestyles” it states:

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

6.83 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 16 – 18 of Schedule 4.

## Prescription linked intervention

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

6.85 The Committee noted SOP 23 ‘Promotion of Healthy Lifestyle & Public Health Campaigns’ under the heading “Identification of patients for promotion of Healthy Lifestyles” states:

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

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

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

*prescription which identifies the patient as having high blood pressure / diabetes etc.*

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

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

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

### **Public health campaigns**

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

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

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

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

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

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

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

### **Signposting**

6.90 The Committee noted that NHS England, in their decision letter, had stated that the Applicant had not demonstrated how it would assess patients' need before signposting them in order to minimise inappropriate use of health and social care services under paragraph 19 of schedule 4.

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

6.92 The Committee noted under SOP 22 'Support for Self-Care, Signposting and Health Promotion' under the heading "Signposting" "Patient identification" states:

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

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

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

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

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

*Other Provider Organisations and Support Details*

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

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

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

### **Support for self-care**

6.94 The Committee noted that NHS England, in their decision letter, had stated that the Applicant had not demonstrated how it would provide advice or support for people caring for themselves or their families under paragraph 21 of schedule 4.

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

6.96 The Committee noted SOP 22 'Support for Self-Care, Signposting and Health Promotion' under the heading "Service outline" states:

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

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

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

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

- 6.97 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 21 – 22 of Schedule 4.
- 6.98 On the information before it, the Committee could be satisfied that there are procedures likely to secure safe and effective provision of essential services as required by Regulation 25(2)(b).
- 6.99 In those circumstances, given the contradictory decision of NHS England as well as the conditions which NHS England had applied to the grant, the Committee determined that the decision of NHS England must be quashed.
- 6.100 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.
- 6.101 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.
- 6.102 The Committee concluded that further notification under paragraph 19 of Schedule 2 would not be helpful in this case.

## **7 Decision**

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

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

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

7.2.3 The application is granted.

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

A copy of this decision is being sent to:

Maneph Resources Ltd  
Sutton Chase, t/a Parade Pharmacy Ltd  
Lloyds Pharmacy  
Pharmacy Thames Valley (the LPC)  
NHS England