1 November 2013

REF: SHA/17268

APPEAL AGAINST NHS COMMISSIONING BOARD (NHS ENGLAND) DECISION TO REFUSE CONNECTED HEALTHCARE LTD'S APPLICATION FOR INCLUSION IN THE PHARMACEUTICAL LIST IN THE VICINITY OF EUROPA STUDIOS, VICTORIA ROAD, NW10 6ND UNDER REGULATION 25 OF THE NHS (PHARMACEUTICAL SERVICES) REGULATIONS 2012 (“THE REGULATIONS”)

1 The Application

By application dated 13 January 2013, Connected Healthcare Ltd ("the Applicant") applied to Ealing Primary Care Trust succeeded by the NHS Commissioning Board (NHS England) for inclusion in the pharmaceutical list 'in the vicinity of Europa Studios, Victoria Road, NW10 6ND' under Regulation 25. In support of the application it was stated:

1.1 Section 6.2 'Pharmacy Procedures' of the application form states:

'Please explain how the pharmacy procedures used within the premises will secure:

(a) The uninterrupted provision of pharmaceutical 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.'

1.2 In response to (a) above, the applicant stated:

1.2.1 The applicant would use national couriers to provide delivery services.

1.3 In response to (b) above, the applicant stated:

1.3.1.1 Telephone fax, letters, health aids-colour coded blisters and leaflets from site.

1.4 The applicant stated that in their view, the application should not be refused pursuant to Regulation 31 as the nearest other pharmacy is over 0.6 miles away.

1.5 The applicant's proposed core opening hours are:

Mon to Fri 9.00am to 5.00pm
Sat Closed
Sun Closed

1.6 The applicant's proposed total opening hours are:

Mon to Fri 9.00am - 5.00pm
1.7 The applicant intends to provide the following services:

Essential services.

Clinical governance.

1.8 Advanced and Enhanced services:

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<td>EHC</td>
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1.9 The applicant stated that they were not undertaking to supply appliances.

2 The Decision

The NHS Commissioning Board (NHS England) considered and decided to refuse the application. The decision letter dated 1 July 2013 states:

Regulation 25 - Distance Selling Premises

2.1 The regulations require that NHS England must refuse an application unless it is satisfied that the pharmacy procedures are likely to secure-

   (i) the uninterrupted provision of pharmaceutical 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.

2.2 The applicant is required to provide evidence or insight into how procedures will fulfil the requirements of the above regulations. The current regulations require NHS England to be satisfied that the pharmacy's procedures are likely to secure these requirements before it can approve the application and not to grant unless it is satisfied. All applications must be fully evidenced since the Pharmaceutical Services Regulations Committee can only determine the application with regard to the evidence provided by the applicant.

2.3 The information provided by the applicant does not satisfy the Pharmaceutical Services Regulations Committee that the pharmacy procedures for the premises will secure the requirements of Regulation 25(2)(i)(ii) and therefore the Committee's decision is not to approve the application.

3 The Appeal
In a letter to the Family Health Services Appeal Unit of the NHS Litigation Authority ("the Appeal Unit") dated 26 July 2013, the applicant appealed against NHS England's decision. The grounds of appeal are:

Pharmacy procedures

(i) the uninterrupted provision of pharmaceutical 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.

3.1 The applicant hopes to illustrate below how they will meet and surpass the essential contract requirements. The applicant's company will provide a local and national service, which will be delivered by both local and national couriers. CDs and cold chain lines will be delivered by specialist couriers who are trained, licensed and validated to handle these special items.

3.2 The applicant has built a robust Quality Management System (QMS) with change control and risk assessment as part of their individual SOP development. The applicant provides to the FHSAU a selection of these SOPs to illustrate their commitment to providing a quality service for their customers who choose to use their pharmacy service. The applicant will monitor their incidents, customer feedback and conduct self audits of procedures to check if staff have understood the applicant's QMS and identify their further training needs and to ensure that customers are happy with the applicant's service. The applicant will regularly review their QMS to keep it up to date and fit for purpose.

3.3 The applicant will dispense medicines, appliances, on acute or repeatable prescriptions with reasonable promptness. A telephone/fax/online internet video system would make it possible for Connected Healthcare to communicate with all patients nationwide without face to face contact.

3.4 The applicant will always inform patients of when their prescription will be delivered to their chosen location. The applicant will provide advice and counselling to the patients by several ways, telephone, email and written consent with their medication. The applicant will provide this service via the patient representatives, carer, if required and if consented.

3.5 The applicant will develop their website to take online payments for patients who have to pay the prescription levy, and for those who are exempt the applicant will record their exemptions and prompt them when they expire.

3.6 The applicant's pharmacy will have temperature loggers logging both the fridge temperature and the ambient storage temperature of the medication. The applicant will store their medicines within the manufacturers guidelines.

3.7 The applicant will put a reminder message on their prescription bags to remind patients not to hoard out of date or unused medicines and to take them to their nearest pharmacy or ask the applicant to arrange a collection for them. The applicant will set up a contract with a suitable provider and will keep records of waste collections.

3.8 The applicant will have their contact telephone number and email on dispensing labels leaflets and on the website thus people can contact the applicant via their chosen route.
3.9 If the applicant has patients who need medical hosiery then they will arrange with their surgery to have them measured fitted, if they are not able to do it themselves. Otherwise the applicant will send them a preform to fill out to illustrate where they want the measurements taken and full instructions on how to take the measurements.

3.10 The applicant will have their own "Repeat Prescription Managed Service", "Practice leaflet", "Information Governance", "Complaints Procedure" and "Electronic Transfer of Prescription" leaflets which can be sent to the patient or emailed. The applicant's leaflets will give guidance on how to reorder medicines and only order what they require and discourage hoarding. The applicant's EPS leaflet will advise patients about EPS and how they can nominate their chosen provider. The applicant's IG leaflet will advise people on how the applicant stores and uses their personal information. The applicant's practice leaflet will advertise their services and will inform patients which services are NHS funded.

3.11 Clinical governance - having standard operating procedures, regular audits and patient feedback would ensure continuous improvements to higher quality standards of patient care. Any complaints would be forwarded to the relevant authorities. Clinical interventions that may be required will be recorded and communicated to the patient or their carer by the chosen route of communication. A secure locked cupboard will be used to store repeat prescriptions and patients will be made aware of owning and the applicant will ask if they wish to have all of their medication delivered at once or in two part deliveries.

3.12 "DAC" prescriptions that the applicant cannot fulfil will be referred to a quality DAC provider, however the applicant will set up an account with the DAC who can provide a customisation service for the applicant. All the applicant's deliveries will be in plain discrete packaging and the applicant will provide wipes and disposal bags. The applicant also provide a signposting service for these patients if they need more clinical advice from a stoma nurse. The applicant will ensure that their pharmacies are up to date with their CPD.

3.13 The applicant's website will carry signposting information, lifestyle and common ailments. Any referral will be recorded and can be audited. Self-care leaflets on key health promotion areas will be sent out with people's prescriptions and on request and each month the website will carry a new health promotion message.

3.14 The applicant will have an appointed clinical governance lead who will be responsible for ensuring the applicant complies and is kept up to date with any changes. The applicant will create an on line survey and action any recommendations or comments. The applicant will take part in at least two audits a year and will publish the results on their website. If the applicant has had any serious incidents they will be reported to NRLS.

3.15 During opening hours the pharmacy would staff a responsible pharmacist for all hours. The lunch break will be covered by a secondary pharmacist.

3.16 When the applicant recruits their staff they will take references and in their induction training they will have to sign a confidentiality agreement. They will be trained in the applicant's QMS and their training will be validated. They will be given protective clothing and they will be encouraged to wash theirs hands regularly to prevent spread of infection. They will also be given training on safeguarding, consent and premises standards. The applicant will also train the staff to deal with recalls.

3.17 The applicant provided the following enclosures with their appeal letter:

3.17.1 A copy of NHS England's decision letter dated 1 July 2013.

3.17.2 Standard Operating Procedure - Delivery of Schedule 2 and 3 Controlled Drugs.
3.17.3 Standard Operating Procedure - Responsible Pharmacist RP10 - Safe and Effective Disposal of Medicines in the Pharmacy.

3.17.4 Standard Operating Procedure - Repeat Dispensing.

4 Summary of Representations

This is a summary of representations received on the appeal.

NHS England

4.1 NHS England wishes to draw to the attention of the appeals authority, that the appellant provides no reason or substance for making the appeal; it just states that it is appealing. Indeed, the appellant does not challenge why or how NHS England came to a decision; rather it provides further information in the form of a letter and Standard Operating Procedures, none of which was provided in its initial application.

4.2 The regulations specifically allow NHS England to request for “missing” information or undertakings. It is a matter for the applicant to decide what information to provide in support of its application at the time of application. There is no restriction to the quantity or content of what is submitted by the applicant, all applications must be fully evidenced. In the case of this application NHS England concluded that there was enough information submitted to bring the application to a decision. To provide additional information, after the decision, seems purposeless.

4.3 By way of background, the appellant has now also submitted a new application, supplying all the same information it has provided for this appeal. Although NHS England understand that one does not prejudice the other, they are curious as to why the applicant had reapplied and appealed at the same time, to the same site, using exactly the same information and criteria for both the appeal and the new application. Surely, one must come to the conclusion that the appellant agrees with the decision made by NHS England and has therefore reapplied, using a new application, and this appeal has been put in only because the appellant has the right to do so, and not because it does not agree with the initial decision made.

4.4 The Appeals Authority has requested that NHS England should deal with each of the matters below in turn. NHS England can only comment taking into regard the initial application submitted as this was the information provided and hence what the decision was made upon.

4.5 With regard to the “new”, “additional” information now supplied in this appeal NHS England shall comment separately.

4.6 With regard to regulation 31 (quoted) there is currently no contractor included in the Pharmaceutical List at the proposed premises or adjacent to it.

In relation to Regulation 25 (quoted) the applicant is not already included in the pharmaceutical list and this is an application for distance selling premises and therefore exempt from Section 129(2A) and (2B) of the 2006 Act(c)

4.7 There is no provider of primary medical services with a patient list on the same site or in the same building as the proposed premises.

4.8 The applicant provided no detail or evidence of “how” it intends to ensure that essential services will be provided to persons anywhere in England who request these services, or “how” it will ensure that service provision is not restricted to certain areas of England or to certain categories of patients.
4.9 A pharmacist is required to be present in the pharmacy throughout core and supplementary opening hours. The physical presence of a pharmacist is required under the Medicines Act 1968 to supervise every transaction involving a pharmacy or prescription only medicine. In addition, the dispensing of any drug or appliance ordered on an NHS prescription has to be done either by or under the direct supervision of a pharmacist. The applicant provided no information or any detail that may be contained in any procedures to ensure these requirements are met.

4.10 The applicant did not state anywhere in the application that it will not be providing any essential services face to face to patients or their representatives, did not explain how its procedures will secure this, or provide any details of what may be contained within any procedures to ensure this. Further more the regulations explicitly state this includes persons who are in the vicinity of the premises; the applicant did not provide any details or evidence of how it will ensure this requirement is fulfilled.

4.11 A distance-selling pharmacy must provide all the drugs and medicines that would be available through a High Street pharmacy when a patient presents a prescription or a prescription is received via the electronic prescription service (EPS). Such a pharmacy cannot refuse to provide certain drugs or medicines. They must dispense all NHS prescriptions and cannot pre-select particular patient groups. The applicant provided no evidence that it has procedures in place to ensure this.

4.12 In particular, the applicant did not explain how it will supply controlled drugs, what audit trails will be in place to ensure safe custody and who will sign the receipt of controlled drugs.

4.13 There were no details of how thermo liable products will be delivered or any auditable cool chain procedures in the original application.

4.14 The pharmacy cannot restrict service provision to only certain categories of patients. How will the applicant ensure that nothing in the practice leaflet, any publicity material or written or oral communications will not suggest that service provision is restricted in this way.

4.15 How will the applicant without “face to face” contact, accept-collect waste and deal with non deliveries.

4.16 A distance-selling pharmacy must provide all medicines with reasonable promptness. Where a distance-selling pharmacy provides certain appliances and hosiery in the normal course of its business, it must dispense against all NHS prescriptions those appliances and hosiery with reasonable promptness. In particular where items require measuring and fitting, this activity cannot take place at the pharmacy premises, how will the applicant ensure that this need is met. How will the applicant respond to a request for acute medication, which is required by the patient without delay.

4.17 How will the applicant provide opportunistic advice as appropriate on healthy living and public health topics. Opportunistic advice is generally given “over the counter” on purchase or enquiry of a medicine, or on collection of prescription medicines. The applicant provided no details of how this will be provided without “face to face” contact, as in the case of a distance selling pharmacy there is no “over the counter” provision.

4.18 Distance-selling pharmacies may provide private services face-to-face at their premises but would however need to ensure that no essential services are provided as a result of attendance of a patient or member of the public at the premises. What procedures does the applicant have in place to ensure that no essential services will be provided inadvertently.
4.19 The applicant stated that it intends to provide advanced and enhanced services, namely, PGD, EHC and Independent/supplementary prescribing, however, provided no floor plan and gave no reason as to why a floor plan cannot be provided.

The Appellants letter to the Appeals Unit dated 26th July 2013

4.20 The appellant states that they have, “a robust Quality Management System (QMS), with change control and risks assessment”,

4.21 a selection of SOPs are supplied, these SOPs are no different to any other being used by any other pharmacy, NHS England cannot find the “change control and risks assessment”, in any of them.

4.22 The appellants states that it will, “dispense “medicines, appliances, on acute or repeatable prescriptions, with reasonable promptness”,

4.23 however, provides no detail of how it will do this, for example how will it provide immediate required antibiotics or palliative care medication to someone in extreme pain requiring them without delay.

4.24 The appellant states that it, “will develop our website to take online payments for patients”

4.25 This implies that this process is not in place at present, and one can only thus conclude that no procedure is therefore in place. The appeals authority will be aware that NHS England must be satisfied that procedures are in place to approve an application.

4.26 With regard to EPS, NHS England's understanding is that it is a requirement for the pharmacy to explain to the patient how the process works, and as part of that explanation a leaflet may be provided, the appellant implies that merely the supply of a EPS leaflet fulfils the requirements to be able to obtain consent to register the patient at its pharmacy.

Standard Operating Procedures

Delivery of Schedule 2 and 3 Controlled Drugs:

4.27 The appellant explains that the purpose of this SOP is “To ensure robust procedures are in place for the safe storage and delivery of cold chain products”

This is not the correct procedure for which it is labelled.

4.28 The appellant only describes a scenario where the patient lives at a distance to which a delivery can be made locally by van. The pharmacy must ensure that it provides services to anyone in England requesting those services. The pharmacy is located in Brent, how will it deliver thermo liable medicaments to patients in Newcastle for example.

4.29 There is no date of review for SOP.

Delivery of Schedule 2 and 3 Controlled Drugs:
Part 6 explains that the "courier driver is effectively the patient's nominated representative, thus authorised to collect and deliver the CD. The courier driver should sign the "collected by" section on the reverse of the prescription."

It should be a matter of choice for the patient who their representative is, and not that of the pharmacy. Furthermore, the guidance from the PSNC directs that signatures on the back of prescriptions should only be made by pharmacy staff in exceptional circumstances, the SOP implies that all CD prescriptions will be signed by delivery drivers with no patient input or choice.

The SOP states that:

"An entry in the CD register should be made when the medication is collected by the courier driver"

What happens in cases of none delivery, particular with respect to legislation and good practice regarding CD entries and also medication that has left the pharmacy premises.

There are no procedures supplied for the following essential services:

- Dispensing
- Promotion of Healthy Lifestyles
- Signposting
- Support for self-care
- Clinical Governance

In Summary:

Regulations 25 – distance selling premise

The regulations require that, the Primary Care Trust must refuse an application unless it is satisfied that the pharmacy procedures 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,

(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.

The Pharmaceutical Services Regulations Committee concluded that it is not satisfied that pharmacy procedures for the pharmacy premises are likely to secure the safe and effective provision of essential services without face to face contact between any person receiving the services,
whether on their own or on someone else’s behalf, and the applicant or the applicant’s staff.

In conclusion

4.39 The Pharmaceutical Services Regulation Committee was correct not to approve the application as it was not satisfied that the applicants pharmacy procedures are likely to secure the requirements of regulation 25(2)(b),(i) and (ii).

Connected Healthcare Ltd (“the Applicant”)

4.40 The applicant's email to the FHSAU dated 20 August 2013, included the following as enclosures:

4.40.1 Promotion of Healthy Lifestyle SOP.
4.40.2 SOP - Safe and effective disposal of medicines Version 3.
4.40.4 Signposting SOP.
4.40.5 Support for Self care SOP.
4.40.6 CG Child Protection Guide.
4.40.7 SOP - dealing with near misses and errors.
4.40.8 SOP - Interventions and Problem Solving.
4.40.9 SOP - Pharmaceutical Assessment.

5 Summary of Observations

This is summary of observations received.

NHS England

5.1 The regulations specifically allow NHS England to request for “missing” information or undertakings. It is a matter for the applicant to decide what information to provide in support of its application at the time of application. There is no restriction to the quantity or content of what is submitted by the applicant, all applications must be fully evidenced. In the case of this application NHS England concluded that there was enough information submitted to bring the application to a decision.

5.2 To provide additional information, after the decision, seems purposeless.

5.3 The application was determined with regard to the information provided by the applicant at the time of application. As stated above NHS England had the option to request for “missing” information. For the applicant to submit further new additional information after the decision, and now yet more information following NHS England's representations seems immaterial in the sense that the FHSAU should be considering the appeal with regard to the initial application and information submitted, as did NHS England at the time of application.

5.4 NHS England appreciate that there is nothing that prohibits the appellant in submitting new information at any stage and the FHSAU taking this into consideration, however, there does come a point where one must consider whether
this is now a “new application” and should be considered as such, following the normal set of processes.

5.5 As stated in NHS England’s previous communication, the applicant has already submitted a “new application” with additional information and this will be determined in accordance with the regulatory framework.

6 Further Comments

Further comments were received from:

Charles Russell LLP (on behalf of the applicant)

6.1 The applicant wishes to respond to representations made by NHS England on the appeal.

6.2 By way of background, the applicant’s proposed premises is within a block of studios. The proposed premises are on the first floor. The building is only accessible through personalised access fobs or by intercom for visitors. As such, the pharmacy premises will not be visible from the street, nor will they be accessible to passers by.

6.3 As the Authority will be aware, NHS England refused the application on the basis that, in its opinion, the applicant had not satisfied NHS England “that the pharmacy procedures for the premises will secure the requirements of regulation 25(2)(i)(ii) ...”.

6.4 By reason of regulation 25(2)(b) NHS England was required to grant the application provided that, amongst other things, it was “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 staff.”

6.5 In its application form and in subsequent representations the applicant set out in detail how it proposes to provide pharmaceutical services to patients who are not present on the premises, irrespective of where they live in England. NHS England had the power to request further information from the applicant regarding its application. NHS England did not request any such information.

6.6 Notwithstanding the information which had previously been given by the applicant and assurances made, NHS England refused the application for the reasons given above.

6.7 The applicant appealed that decision and provided the NHS Litigation Authority with copies of its Standard Operating Procedures to demonstrate that the requirements of regulation 25 are met.

6.8 As the Authority is aware, it must re-determine the application from new. The applicant’s appeal is not a review of the lawfulness of NHS England’s decision but a reconsideration of all relevant matters. Whether or not the applicant provided particular information to NHS England is therefore not relevant to the determination of this appeal. Similarly, it is irrelevant whether the applicant has submitted a fresh application to NHS England.

6.9 In relation to the requirements of regulation 25, the Authority should now be satisfied that, for each of the essential services, the requirements of regulation 25 are met. Taking each service in turn the applicant comments as follows:-
THE DISPENSING OF PRESCRIPTIONS/PRESCRIPTION LINKED INTERVENTION

6.10 The applicant has provided the Authority with the following SOPs which are linked to this essential service: Interventions and Problem Solving; Pharmacy Patient Safety Incident Report and Follow Up and Incident Report forms; Pharmaceutical Assessment; Advice, Intervention and Referral form; Dealing with Near Misses and Errors; Delivery of Schedule 2 and 3 Controlled Drugs; Child Protection; Storage and Delivery of Cold Chain Drugs; Repeat Dispensing.

6.11 In addition, the applicant encloses with this letter a copy of the following SOPs: Taking in Prescriptions; Assembling and Labelling Prescriptions; Final Check by Pharmacist; Delivery of Prescriptions.

6.12 Taken together these SOPs demonstrate how the applicant will provide a safe and effective service to patients no matter where they live in England having regard to the fact that there will be no face to face contact between the patient and the pharmacist or pharmacy staff.

DISPOSAL OF UNWANTED DRUGS

6.13 The applicant has already provided its SOP for the Safe and Effective Disposal of Medicines in the Pharmacy. This SOP demonstrates how the essential service of the disposal of unwanted medicines will be provided safely and effectively to patients no matter where they live in England and having regard to the fact that patients will not have to face to face contact with the pharmacist or pharmacy staff.

PROMOTION OF HEALTHY LIFESTYLES/PUBLIC HEALTH CAMPAIGNS

6.14 The applicant has already provided to the Authority a copy of its SOP for the Promotion of Healthy Lifestyles (Public Health) (which deals both with the promotion of healthy lifestyles and participation in public health campaigns). This SOP demonstrates how the applicant will provide these essential services safely and effectively to patients no matter where they live in England and having regard to the fact that patients will not have to face to face contact with the pharmacist or pharmacy staff.

SIGNPOSTING

6.15 The applicant has already provided its SOP for the signposting procedure. This SOP demonstrates to the Authority how the applicant will provide this essential service safely and effectively no matter where patients live in England and having regard to the fact that patients will not have face to face contact with the pharmacist or pharmacy staff.

SUPPORT FOR SELF-CARE

6.16 The applicant has already provided to the Authority its SOP dealing with support for self-care. This SOP demonstrates how the applicant will provide that service safely and effectively to patients no matter where they live in England and having regard to the fact that patients will not have face to face contact with the pharmacist or pharmacy staff.

6.17 For the avoidance of doubt, the applicant encloses with this letter a copy of all of the SOPs referred to above. Having regard to the SOPs enclosed with this letter and the information previously given both to the Authority and to NHS England by the applicant, the Authority should be satisfied that the requirements of regulation 25 are met and must grant this application.
In relation to the additional matters raised by NHS England, the applicant comments as follows:-

6.18.1 It is a requirement of the Terms of Service that medicines must be supplied with "reasonable promptness". What amounts to "reasonable promptness" will depend on the circumstances of each case. Since there is specific provision within the Regulations for inclusion in the pharmaceutical list through the operation of a distance selling pharmacy, it is implicit in the Regulations that pharmacists may comply with the obligation to provide medicines with "reasonable promptness" whilst being unable to have face to face contact with patients and being required to provide medicines and other services to patients no matter where they are in England. The applicant's procedures as supplied to the Authority demonstrate how it will provide all essential services and comply with its Terms of Service.

6.18.2 It is not surprising that the applicant's website is not yet "up and running" since the application for inclusion in the pharmaceutical list has not yet been granted. However, the procedures which have been provided demonstrate how the pharmacy will operate. It is not necessary for the Authority to view the applicant's website (or any other literature) to be satisfied that appropriate procedures are in place.

6.18.3 It is not accepted that the applicant's SOP relating to the Delivery of Schedule 2 and 3 Controlled Drugs "only describes a scenario where the patient lives at a distance to which a delivery can be made locally by van". The SOP specifically refers to the use of a courier company for the delivery of medicines (such as "ecouriers"). The selected courier will provide a nationwide delivery service where required.

6.18.4 Reference to the courier driver being "the patient's nominated representative" merely reflects the requirements of the NHS Terms of Service and the Human Medicines Regulations 2013 that medicines must be supplied at (from) registered pharmacy premises which are included in the pharmaceutical list. The supply to the patient is therefore deemed to have been made when the medicines are collected by the delivery driver. That is the same as all English pharmacies which provide medication delivery services.

6.18.5 The SOP for the Delivery of Prescriptions sets out in detail what will happen if the patient is not available to receive the delivered medication.

6.18.6 In relation to EPS, the applicant will provide all necessary information to patients (whether by way of a leaflet, telephone advice or electronic communication), although there is no obligation to provide information as suggested by NHS England.

For the reasons given above and those given by the applicant previously, the Authority is invited to uphold the appeal and grant the application.

Charles Russell's letter included the following as enclosures:

6.20.1 SOP - Taking in Prescriptions.

6.20.2 SOP - Assembling & Labelling Prescriptions.

6.20.3 SOP - Pharmaceutical Assessment.

6.20.4 SOP - Final Checks by Pharmacist.

6.20.5 SOP - for Final Check.
6.20.6 SOP - Delivery of Prescriptions.
6.20.7 SOP - Storage and Delivery of Cold Chain Drugs.
6.20.8 SOP - Delivery of Schedule 2 & 3 Controlled Drugs.
6.20.9 SOP - Repeat Dispensing.
6.20.10 SOP - Dealing with Near Misses and Errors.
6.20.11 SOP - Support for Self Care.
6.20.12 SOP - Signposting Procedure.
6.20.13 SOP - Promotion of Healthy Lifestyles.
6.20.14 SOP - Responsible Pharmacist RP10 - Safe and Effective Disposal of Medicines in the Pharmacy.
6.20.15 SOP - Interventions and Problem Solving.

7 Consideration

7.1 The Pharmacy Appeals Committee appointed by the Family Health Services Appeal Unit of the NHS Litigation Authority, (“the Committee”) had before it the papers considered by NHS England, together with a plan of the area showing existing pharmacies and doctors’ surgeries and the site of the proposed pharmacy.

7.2 It also had before it the responses to the Authority’s own statutory consultations.

7.3 On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.

7.4 The Committee dealt with the application by way of reconsideration of all the issues.

7.5 The Committee had regard to Regulation 25 of the National Health Service (Pharmaceutical Services) Regulations 2012 (“the Regulations”) which reads as follows:

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

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

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

in respect of pharmacy premises that are distance selling premises.

(2) The Primary Care Trust 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 Primary Care Trust 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.”

7.6 The Committee also had regard to Regulation 31 (Refusal: same or adjacent premises) and to the provisions of Schedule 2 to the Regulations shown below:

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

6. If, as regards a routine or excepted 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 also in respect of premises other than those already listed in relation to that person,

the premises which the applicant (A) is seeking to be listed in relation to A are already listed chemist premises or are adjacent to or in close proximity to such premises, A must include with the application details that explain why A believes the application should not be refused pursuant to regulation 31.

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 Primary Care Trust in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Primary Care Trust may need to make of the information or documentation when carrying out its functions.

Relevant information or documentation
11. (1) As regards any routine or excepted application, if the Primary Care Trust to which the application is made considers that relevant information or documentation is missing—

(a) it may request the missing relevant information or documentation from the applicant; and

(b) the applicant must, within the period reasonably specified by the Primary Care Trust in the request under paragraph (a)—

(i) provide any information or documentation reasonably requested,

(ii) notify the Primary Care Trust that there is to be a delay in providing the requested information or documentation, for specified reasons, and specify a date by which the applicant undertakes to provide the information or documentation, or

(iii) if the applicant considers that any information or documentation has been unreasonably requested, notify the Primary Care Trust of that and seek a review by the Primary Care Trust of the reasonableness of the request.

(3) A Primary Care Trust may request information or documentation under this paragraph at any time after it receives an application and before its determination of that application, but it must consider whether or not it needs to request information or documentation under this paragraph prior to notifying an application (where it is required to do so) under Part 3.

7.7 In relation to Regulation 31, the Committee noted that in the application form, the Applicant states that in their view, the application should not be refused pursuant to Regulation 31 as the nearest other pharmacy is over 0.6 miles away. The Committee noted that this had not been disputed, nor was the Committee provided with any information to dispute the applicant’s statement. In the circumstances, the Committee was satisfied that the proposed premises were not adjacent to, or in close proximity to other chemist premises.

7.8 Paragraph 8 of Schedule 2 requires the Applicant to include information in the application in relation to (a) criteria in the relevant regulation about which the decision maker must be satisfied, and (b) why any matters in the relevant regulation which would require the application to be refused do not apply.

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

7.10 As far as Regulation 25(2)(a) is concerned, the Committee had no information to show that the proposed premises are on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

7.11 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 Standard Operating Procedures (SOPs) that they intend to use at the proposed pharmacy premises, for the provision of essential services.
7.12 The Committee noted several SOPs have been submitted as part of the appeal process. The Committee noted NHS England's concerns at 4.8 to 4.40 above, then further noted the information now supplied by the Applicant who has addressed these concerns.

7.13 Where a person is required to provide details in relation to an application, paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy the Primary Care Trust in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Primary Care Trust may need to make of the information or documentation when carrying out its functions.

7.14 The Committee has asked itself whether it has sufficient information and documentation before it upon which it can be satisfied that there are procedures likely to secure uninterrupted, safe and effective provision of essential services without face to face contact in accordance with regulation 25(2)(b)(i) and (ii).

7.15 The Committee noted the detailed requirements set out in Part 2 of Schedule 4 to the Regulations. The Committee then noted the information that had now been provided by the Applicant; copies of SOPs that the Applicant has in place for the proposed pharmacy as referred to in paragraphs 3.17.2 to 3.17.4, paragraphs 4.41 to 4.41.9 and 6.21.1 to 6.21.15 above. These SOPs also include procedures regarding Assembling & Labelling Prescriptions, Delivery of Prescriptions, Support for Self Care, with each SOP explaining what the operating procedures are, whose responsibility it is to manage and declarations for the intended user to fill in and sign off.

7.16 The Committee noted the Applicant's submissions in respect of the provision of services and paid particular regard to the SOPs now provided.

7.17 The Committee noted NHS England's comment that the applicant had not shown that a pharmacist would be present in the pharmacy throughout core and supplementary opening hours. The Committee noted that the applicant's core opening hours are Monday to Friday 9.00am to 5.00pm. On appeal, the applicant had stated "During opening hours the pharmacy would staff a responsible pharmacist for all hours. The lunch break will be covered by a secondary pharmacist."

7.18 The Committee considered that the Applicant had provided thorough and detailed SOPs explaining how items will be dispensed using a courier, explaining how stock is to be controlled and delivery methods for controlled drugs and fridge items. The Committee was satisfied with the detailed explanations of how prescriptions will be received, prepared and dispatched within the pharmacy without face to face contact. The Committee also noted that the Applicant had provided information to explain how Owings of medicines will be dealt with and how dispensing errors will be handled within the pharmacy.

7.19 The Committee was satisfied that the Applicant had provided sufficient detail with regard to systems in place for the disposal of unwanted medicines including the receipt and/or collections from patients, the disposal of out of date stock, the storing of items on site in specialised bins, the handling of such items and then the transferring of the waste to a specialist waste disposal company.

7.20 The Committee was satisfied that the Applicant had provided sufficient detail with regard to signposting and support for self care. The Committee was satisfied that the Applicant intended to be actively involved in promoting public health including through booklets and leaflets.

7.21 The Committee noted that all staff will be appropriately trained to deliver the highest standards of Clinical Governance, with their activities being guided by the Applicant's SOPs which will be available to all staff.
7.22 The Committee noted that, in paragraph 4 of the application form, the applicant has confirmed that he will not be providing appliances (by the inclusion of the word "None" in the relevant box)."

7.23 The Committee noted the content of paragraph 11(3) which obliges NHS England to consider whether or not it needs to request information or documentation under paragraph 11 prior to notifying an application under Part 3 of Schedule 2. The Committee was of the view that NHS England had undertaken such a consideration and determined that it need not request further information from the Applicant. While NHS England elected not to seek further information, the Committee considered that it may well have exercised these powers to obtain SOPs although, in this case, the applicant provided such information without the need to do so. As the applicant points out, it is not the Committee's role to conduct a review of the NHS England decision making, but rather to consider afresh the application. The Committee must consider the application in light of the situation as it is at the time of the appeal, including all material which it considers relevant.

7.24 In overall consideration of the information and reassurances provided by the Applicant in the appeal and in response to issues raised by interested parties, the Committee 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, whether on their own or on someone else's behalf, and the Applicant or the Applicant's staff. In arriving at this decision the Committee is mindful that the detailed application of the Standard Operation Procedures referred to in the reassurances given is something to be monitored by the commissioning and regulatory bodies.

8 Decision

8.1 Accordingly, the Committee:

8.1.1 quashes the decision of NHS England; and

8.1.2 redetermines the application as follows:

8.1.2.1 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;

8.1.2.2 the Committee was satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises;

8.1.2.3 the Committee was satisfied that the provision of essential services would be undertaken without interruption for persons anywhere in England;

8.1.2.4 based on the information provided, the Committee was satisfied that the safe and effective provision of all essential services was likely to be secured by the Applicant without face to face contact.

8.1.3 The appeal is allowed, and therefore the application is approved in so far as that which was applied for which did not include the provision of appliances.

Ray Bushell
FHSAU Case Manager
A copy of this decision is being sent to:

Mr N Wardle, Charles Russell LLP - on behalf of the applicant
S S Bansal, Primary Care Commissioning Manager -
Pharm Control of Entry - NHS England