

25 September 2020

Arena Point
Merrion Way
Leeds
LS2 8PA

REF: SHA/23379

APPEAL AGAINST SOUTH EAST AREA TEAM, NHS COMMISSIONING BOARD ("NHS ENGLAND") DECISION TO REFUSE AN APPLICATION BY WAREMOSS LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST OFFERING UNFORESEEN BENEFITS UNDER REGULATION 18 AT 152 – 154 HIGH STREET, UCKFIELD, EAST SUSSEX, TN22 1AT

Tel: 0203 928 2000
Fax: 0207 821 0029
Email: appeals@resolution.nhs.uk

1 Outcome

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

Advise / Resolve / Learn

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1 The Application

By application dated 16 December 2019, Waremass Ltd ("the Applicant") applied to NHS Commissioning Board ("NHS England") for inclusion in the pharmaceutical list offering unforeseen benefits under Regulation 18 at 152 – 154 High Street, Uckfield, East Sussex, TN22 1AT. In support of the application it was stated:

1.1 Proposed core opening hours:

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total
9am to 6pm	9am to 6pm	9am to 6pm	9am to 6pm	9am to 6pm	9am to 5pm		53
Core hours to also be provided each Christmas Day and Easter Sunday of 11am to 2pm							

1.2 Total proposed opening hours:

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total
9am to 6pm	9am to 6pm	9am to 6pm	9am to 6pm	9am to 6pm	9am to 5pm		53
Core hours to also be provided each Christmas Day and Easter Sunday of 11am to 2pm							

1.3 In response to why the application should not be refused pursuant to Regulation 31, the Applicant did not complete this section and left it blank.

In response to "Please describe the unforeseen benefit(s) that you are offering to secure and how it will secure improvements or better access to pharmaceutical services, or pharmaceutical services of a specified type in the HWB's area." The Applicant stated:

1.4 Uckfield is a town situated just to the south of the rural High Weald area of East Sussex. On most days, the pharmaceutical service in Uckfield is adequate. However, on Christmas Day and Easter Sunday there are no pharmaceutical services except rotas which may be commissioned by NHSE & NHSI.

1.5 The rotas provide a limited pharmaceutical service of a few hours to patients who can attend the pharmacy. However, the last census shows that there are over 1,000 households in Uckfield alone without a vehicle which equates to over 13% of the households.

(ref:<https://www.nomisweb.co.uk/reports/localarea?compare=E34004591> accessed 16/12/19)

- 1.6 These 1,000 plus households or over 2,400 people (there are 7643 households and a population of 18,452) may have difficulty accessing pharmaceutical services on Easter Sunday and Christmas Day. Bus services are minimal during the week, as would be expected for a rural area but on Christmas Day there are no bus, train or other public transport services whatsoever.
- 1.7 Therefore, if a patient is ill and unable to get out of the house then if in one of the 1,000 plus households without a car they may have great difficulty getting someone to attend the pharmacy for them to access, for example, the community pharmacist consultation service to access medicines.
- 1.8 There is no mention in the Pharmaceutical Needs Assessment regarding access to services for those without cars on days when there is no public transport provision whatsoever.
- 1.9 An innovative unforeseen benefit offered within this application is that the contractor will sign an undertaking to commit to open the pharmacy from 11 am to 2pm on every Easter Sunday and Christmas Day, without additional payment. These will be regarded as core hours with any breach of opening to be treated with the same breach notice and market exit proceedings as for any other breach of contracted opening hours on a rota day. Please note that Waremooss Ltd has never received a breach notice and intend to maintain that record.
- 1.10 In addition to this commitment, to open on Christmas Day and Easter Sunday, as a further innovative unforeseen benefit the contractor commits to also provide a free of charge delivery service during opening hours of medicines to those unable to get to the pharmacy. Anyone within the areas of Uckfield and the rural areas of Buxted, Maresfield, Little Horsted, Framfield, Blackboys will also be entitled to receive a free delivery of urgently needed medicines during the opening hours of the pharmacy on Christmas Day and Easter Sunday. A normal free medication delivery service will also be provided on every other weekday that the pharmacy is open.
- 1.11 The Applicant would be willing to sign a standard NHS local enhanced service contract so that NHSE & NHSI can be assured of the full commitment of the contractor to provide the free medicine delivery service on each weekday as well as Christmas Day and Easter Sunday.
- 1.12 The Executive Summary of the current Pharmaceutical Needs Assessment (July 2017) states
"Where people have access to a car there is adequate access in terms of travel times to a pharmacy in all parts of the county, including weekends. However, over a third of pensioner households do not have access to a car."
- 1.13 On page 34 it says "(from 2014 to 2020) At district/borough level Wealden is predicted to see the biggest percentage change in its population (a 4% increase). It is also predicted to see the biggest percentage increase in those aged 85 years and over (a 25% increase)."
- 1.14 On page 77 it shows that in Wealden, 27.7% of pensioner households do not have a car.
- 1.15 On page 104, the results of patient surveys regarding views about ease of access to pharmacies in High Weald Lewes and Havens CCG are listed. Yet, no one appears to have been asked about access on Easter Sunday or Christmas Day when these are the days when access is hardest.

- 1.16 Despite all of the evidence listed of a significantly increasing elderly population and the large number of (particularly) pensioner households without a car the PNA makes no mention of any difficulties accessing pharmaceutical services on Easter Sunday and Christmas Day. Yet, the evidence indicates that this is an issue for those without access to a vehicle.
- 1.17 This application provides two innovative and unforeseen benefits that will provide a more comprehensive pharmaceutical service and the Applicant respectfully requests that it is approved.

In response to "Please explain how you intend to secure the unforeseen benefit(s)." the Applicant stated:

- 1.18 The pharmacy will offer the stated advanced services-
- 1.18.1 CPCS,
 - 1.18.2 MURs,
 - 1.18.3 NMS,
 - 1.18.4 flu vaccinations
- 1.19 In addition will sign contracts with NHSE & NHSI to offer the following unforeseen benefit enhances services, without payment:
- 1.19.1 open as core hours from 11 am to 2pm every Christmas Day and Easter Sunday
 - 1.19.2 provide a free medicine delivery service every weekday, Christmas Day and Easter Sunday, offered throughout opening times
- 1.20 All locally commissioned public health services will also be offered:
- 1.20.1 NHS Health Checks
 - 1.20.2 Supervised Administration services
 - 1.20.3 Sexual Health Services
 - 1.20.4 Health Living Pharmacy advanced level
 - 1.20.5 Substance Misuse Service
 - 1.20.6 Smoking Cessation Service
 - 1.20.7 Any other commissioned service
- 1.21 The longest core opening hours of any pharmacy in Wealden will be available.

2 **The Decision**

NHS England considered and decided to refuse the application. The decision letter dated 3 July 2020 states:

- 2.1 NHS England has considered the above application and is writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.

Extract from the PSRC Meeting of 27 May 2020

- 2.2 An unforeseen benefits application had been received from the Applicant trading as Kamsons Pharmacy, on 20th December 2019.
- 2.3 The Committee was now required to consider the application in accordance with Regulations 18 and 19 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.

CONSIDERATION

- 2.4 The Committee considered the following:
- 2.5 The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.
- 2.6 The application form provided by the applicant –
- 2.6.1 The Committee noted that the applicant was proposing to provide essential, enhanced and advanced services, if commissioned.
- 2.6.2 The applicant also proposed core opening of 53 hours per week and total proposed opening of 53 hours per week.
- 2.6.3 The Committee considered the applicants statement as to the unforeseen benefits it is offering. The Applicant has stated that *'Uckfield is a town situated just to the south of the rural High Weald area of East Sussex. On most days, the pharmaceutical service in Uckfield is adequate. However, on Christmas Day and Easter Sunday there are no pharmaceutical services except rotas which may be commissioned by NHSE & NHSI.*
- 2.6.4 *The rotas provide a limited pharmaceutical service of a few hours to patients who can attend the pharmacy. However, the last census shows that there are over 1,000 households in Uckfield alone without a vehicle which equates to over 13% of the households.*
- 2.6.5 *These 1,000 plus households or over 2,400 people (there are 7,643 households and a population of 18,452) may have difficulty accessing pharmaceutical services on Easter Sunday and Christmas Day. Bus services are minimal during the week, as would be expected for a rural area but on Christmas Day there are no bus, train or other public transport services whatsoever.*
- 2.6.6 *Therefore, if a patient is ill and unable to get out of the house then if in one of the 1,000 plus households without a car they may have great difficulty getting someone to attend the pharmacy for them to access, for example, the community pharmacist consultation service to access medicines.*
- 2.6.7 *There is no mention in the Pharmaceutical Needs Assessment regarding access to services for those without cars on days when there is no public transport provision whatsoever.*
- 2.6.8 *An innovative unforeseen benefit offered within this application is that the contractor will sign an undertaking to commit to open the pharmacy from 11am to 2pm on every Christmas Day and Easter Sunday, without additional payment. These will be regarded as core hours with any breach of opening to be treated with the same breach notice and market exit proceedings as for any other breach of contracted opening hours on a rota day. Please note that Waremooss Ltd has never received a breach notice and we intend to maintain that record.*

- 2.6.9 *In addition to this commitment, to open on Christmas Day and Easter Sunday, as a further innovative unforeseen benefit the contractor commits to also provide a free of charge delivery service during opening hours of medicines to those unable to get to the pharmacy. Anyone within the areas of Uckfield and the rural areas of Buxted, Maresfield, Little Horsted, Framfield, Blackboys, will also be entitled to receive a free delivery of urgently needed medicines during the opening hours of the pharmacy on Christmas Day and Easter Sunday. A normal free medication delivery service will also be provided on every other weekday that the pharmacy is open.*
- 2.6.10 *Waremass Ltd would be willing to sign a standard NHS local enhanced service contract so that NHSE & NHSI can be assured of the full commitment of the contractor to provide the free medicine delivery service on each weekday as well as Christmas Day and Easter Sunday.'*
- 2.6.11 The information submitted by the Applicant along with the application indicates that the Applicant proposes to provide pharmaceutical services to the residents of Uckfield from the proposed location. The Applicant had also stated that 'The Executive Summary of the current Pharmaceutical Needs Assessment (July 2017) states:
- 'Where people have access to a car there is adequate access in terms of travel times to a pharmacy in all parts of the county, including weekends. However, over a third of pensioner households do not have access to a car. On page 34 it says "(from 2014 to 2020) At district/borough level Wealden is predicted to see the biggest percentage change in its population (a 4% increase). It is also predicted to see the biggest percentage increase in those aged 85 years and over (25% increase)."*
- 2.6.12 *On page 77 it shows that in Wealden, 27.7% of pensioner households do not have a car.*
- 2.6.13 *On page 104, the results of patient surveys regarding views about ease of access to pharmacies in High Weald Lewes and Havens CCG are listed. Yet, no-one appears to have been asked about access on Easter Sunday or Christmas Day when these are the days when access is hardest.*
- 2.6.14 *Despite all of the evidence listed of a significantly increasing elderly population and the large number of (particularly) pensioner households without a car the PNA makes no mention of any difficulties accessing pharmaceutical services on Easter Sunday and Christmas Day. Yet, the evidence indicates that this is an issue for those without access to a vehicle.*
- 2.7 The Committee Report and annexes prepared by Primary Care Support England (PCSE) and NHS England:
- 2.7.1 The Committee noted that the applicant's fitness to practise had previously been considered and approved.
- 2.7.2 All additional information, including location, opening times and distances of surrounding pharmacies and GP Surgeries were noted and considered by the Committee.
- 2.8 The Committee considered the representations made by the Applicant – and noted the comments made by the interested parties:
- 2.8.1 **East Sussex Local Pharmaceutical Committee (LPC)** – *'In considering this application, NHS England will first need to consider regulations 36, 37 and 31. Regarding the unforeseen benefits considerations, we make the following observations:*

- 2.8.2 *The summary of pharmacy provision in East Sussex PNA 2017 said – overall, however, there is good service pharmaceutical provision across East Sussex. Since publication in July 2017, we note that updated information has been dealt with through the process of issuing supplementary statements and that this new information did not affect Uckfield or surrounding areas.*
- 2.8.3 *Arrangements for Christmas and Easter opening in East Sussex – Public holiday opening hours are largely serviced by voluntary opening arrangements covered by supplementary hours. Christmas Day and Easter Sunday are covered by an enhanced service directed rota, commissioned by NHS England. A payment is made to the contractor to cover these hours.*
- 2.8.4 *The PNA in July 2017 had a recommendation for NHS England to review the extended hours rota scheme for community pharmacy considering the PNA findings, which we understand was completed. This resulted in agreements being reached for pharmacies to open on Christmas Day and Easter Sunday for four hours at the same pharmacy from one year to the next to enable people to access a local service. This will further be reviewed when these agreements are due for renewal later this year.'*
- 2.8.5 **Boots UK Ltd** – *'The applicant has not provided any evidence of the residents in Uckfield experiencing difficulties when accessing pharmaceutical provision in this locality, services nor has the applicant provided any indication that patients who share a protected characteristic do not have access to services to meet any specific needs.*
- 2.8.6 *There are four pharmacies within a mile of the proposed location. Our pharmacy at 11 High Street Uckfield is located approximately 250 metres (0.1mile) from the application site. We are not aware of any patients having difficulty accessing our pharmacy. Extended hours provision is provided by Tesco who are open 78 hours a week and are located 0.3 miles away.*
- 2.8.7 *Furthermore, there is no evidence to suggest patients do not currently have access to a reasonable choice of pharmaceutical services or that the application is based on innovative approaches to the delivery of pharmaceutical services. By the applicant's own submission, in section 6 they state that 'on most days, the pharmaceutical service in Uckfield is adequate'.*
- 2.8.8 *With regard to access on Christmas Day and Easter Sunday, Schedule 4, Part 3, Regulation 23(12) states: 'For the purpose of calculating the number of hours that pharmacy premises are open during a week that includes Christmas Day, Good Friday, Easter Sunday or a bank holiday, it is to be deemed that the pharmacy premises were open on that day at the times at which they would ordinarily have been open on that day of the week'.*
- 2.8.9 *The Pharmacy Manual states: 'Contractors are not required to open on public (Christmas Day and Good Friday) or bank holidays (including any specially declared bank holidays). In addition, they are not required to open on Easter Sunday, which is neither a public nor bank holiday. They are encouraged to notify NHS England well in advance so that consideration can be given as to whether the provision of pharmaceutical services on these days will meet the reasonable needs of patients and members of the public'.*
- 2.8.10 *With this in mind, there should not be a gap in pharmaceutical provision at such times that would warrant the need for an additional pharmacy in this locality.'*
- 2.9 Department of Health guidelines on market entry by means of pharmaceutical needs assessment – Chapter 8 – Unforeseen Benefits

- 2.10 Department of Health guidance on Market Entry by means of pharmaceutical needs assessment – Chapter 14 – provision of pharmaceutical services in controlled localities
- 2.11 Regulation 31 – Refusal: same or adjacent premises
- 2.12 The Committee considered Regulation 31(2)(a)(i) and was of the view that Regulation 31(2)(a)(i) is not met as there is currently no person on the pharmaceutical list at the premises to which the application relates.
- 2.13 The Committee went on to consider paragraph (a)(ii) of Regulation 31(2); whether there is a person on the pharmaceutical list providing pharmaceutical services from adjacent premises
- 2.14 The Committee was satisfied that 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.
- 2.15 The Committee decided that it was not necessary to hold an oral hearing before determining the application.

DECISION

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

REASONS FOR DECISION

- 2.17 The reasons for this decision are as follows:
- 2.18 Pharmaceutical Needs Assessment (PNA)
- 2.19 The Committee had regard to the East Sussex Pharmaceutical Needs Assessment (the 'PNA') and noted that supplementary statements had not been issued.
- 2.20 The Committee also noted that, having considered the entire East Sussex area including Uckfield, the HWB had reached the conclusion that 'Overall, however, there is good service pharmaceutical provision across East Sussex. Where the area is rural there are enough dispensing practices to provide essential dispensing services to the rural population. There are areas where population may increase due to housing development, however this may not affect pharmaceutical service provision within the lifetime of this PNA (page 13)'.
- 2.21 The Committee noted that the HWB had considered access (distance, travelling times and opening hours') to assess how current service provisions will meet the needs of the population within the lifetime of the PNA.

Regulation 18 – Unforeseen benefits applications: additional matters to which the NHSCB must have regard

- 2.22 Further to Regulations 18(1), the Committee was required to consider whether it is satisfied that granting the application or granting it in respect of some of the services specified in it, would secure improvements or better access, to pharmaceutical services; and the improvements or better access that would be secured were or was not included in the relevant PNA.
- 2.23 In order to be satisfied in accordance with Regulation 18(1), the Committee went on to consider those matters set out at Regulation 18(2).

Regulation 18(2)(a)(i) - whether or not granting the application would cause significant detriment to the proper planning in respect of the provision of pharmaceutical services.

- 2.24 The Committee was not aware of any plans that would be affected and concluded that granting the application would not have an adverse effect on any future plans.

Regulation 18(2)(a)(ii) - whether or not granting the application would cause significant detriment to the arrangements in place for the provision of pharmaceutical services.

- 2.25 The Committee found no evidence that if the application was to be granted, it would cause significant detriment to the arrangements in place for pharmaceutical services in the area.

- 2.26 The Committee did not find any significant detriment to proper planning or to the arrangements in place for the provision of pharmaceutical services and therefore was not obliged to refuse the application under Regulation 18(2)(a).

Regulation 18(2)(b)(i) – whether notwithstanding that the improvements or better access were not included in the relevant PNA, it is satisfied that, having regard in particular to the desirability of – there being a reasonable choice with regard to obtaining pharmaceutical services in the area of the relevant HWB – granting the application would confer significant benefits on persons in the area of the relevant HWB which were not foreseen when the relevant PNA was published.

- 2.27 In order to determine if patients in the area already had a reasonable choice, the Committee considered access (distance, travelling times and opening hours) as an important factor in determining the extent to which the current pharmaceutical service provision meets the needs of the population in the Uckfield area.

- 2.28 The Committee had regard to the current service provision in the immediate area of Uckfield and noted that there are three pharmacies within 0.6km of the proposed premises, one of which is within a Tesco store, with plenty of parking available. There is also another pharmacy within 1.5km.

- 2.29 The weekday core opening hours of the four pharmacies range from 08:30 to 18:00, Saturday core opening hours range from 09:00 to 14:00.

- 2.30 The Committee noted that the applicant had offered to open 09:00-18:00 Mon-Fri and 09:00-17:00 Sat and closed on Sundays. However, there were already pharmacies in the area providing the same weekday core hours but shorter core hours on Saturdays as indicated above

- 2.31 The Committee also noted that patients in the area of Uckfield also had a reasonable choice as to which providers from which to access pharmaceutical services. Including one Boots, two Kamsons and a Tesco.

- 2.32 The Committee noted that NHS England commissions and directs rota services on Christmas Day and Easter Sunday as appropriate.

- 2.33 Having considered the factors above, the Committee was satisfied that residents of Uckfield already had reasonable choice with regard to obtaining pharmaceutical services.

- 2.34 The Committee noted that bus services in the area are good.

Regulation 18(2)(b)(ii) - whether notwithstanding that the improvements or better access were not included in the relevant PNA, it is satisfied that, having regard in particular to the desirability of – people who share a protected characteristic having access to services that meet specific needs for pharmaceutical services that, in the area of the relevant HWB, are difficult for them to access - granting the application

would confer significant benefits on persons in the area of the relevant HWB which were not foreseen when the relevant PNA was published.

- 2.35 The Committee received no evidence that identified a group of patients in the Uckfield area, sharing a protected characteristic who had difficulty accessing services that meet a specific need. The Committee therefore concluded that the application did not satisfy the criteria in this part of the Regulation.

Regulation 18(2)(b)(iii) - whether notwithstanding that the improvements or better access were not included in the relevant PNA, it is satisfied that, having regard in particular to the desirability of – there being innovative approaches taken with regard to the delivery of pharmaceutical services - granting the application would confer significant benefits on persons in the area of the relevant HWB which were not foreseen when the relevant PNA was published.

- 2.36 The Committee agreed that there is no evidence that an innovative approach would be taken with regard to the delivery of pharmaceutical services. The applicant refers to a delivery service as an innovation. However, the Committee considered that this is a service provided by many pharmacies and could not be considered as an innovation.

- 2.37 Regulation 18(2)(c)-(f) - The Committee had previously determined that there was no need to defer the application under Regulation 18(2)(c) to (f).

- 2.38 The Committee concluded that Regulation 18(2)(b) had not been met because:

2.38.1 there is already a reasonable choice with regard to obtaining pharmaceutical services,

2.38.2 there is no evidence of people sharing protected characteristics having difficulty in accessing pharmaceutical services, and

2.38.3 there is no evidence that innovative approaches would be taken with regard to the delivery of pharmaceutical services.

- 2.39 The Committee was not satisfied that granting the application would confer significant benefits or secure improvements and better access to pharmaceutical services.

RIGHTS OF APPEAL

- 2.40 The application is refused so the applicant has rights of appeal.

- 2.41 There are no third-party appeal rights as the application is refused.

3 The Appeal

In the online form for pharmacy application appeals dated 22 July 2020 addressed to NHS Resolution, the Applicant appealed against NHS England's decision. The grounds of appeal are:

- 3.1 This was an unforeseen benefits application which offered the unforeseen benefit of opening on Christmas Day and Easter Sunday with a free, contracted, delivery service of medicines on these days to patients in Uckfield and the surrounding villages. This would be of great benefit to the over 1,000 households without access to a car.

- 3.2 This innovative unforeseen benefit, which the Applicant does not know of existing anywhere else, was dismissed without proper consideration by NHS England as "... *The applicant refers to a delivery service as an innovation. However the Committee considered that this is a service provided by many pharmacies and could not be considered as an innovation.*"

- 3.3 The Applicant respectfully requests that the decision of NHS England is quashed and reconsidered.

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 NHS ENGLAND

4.1.1 The South East Pharmaceutical Services Regulations Committee has considered the content of the appeal and has no further comments to add at this stage.

4.1.2 Therefore, the Committee retains its view that the application should be refused.

4.2 BOOTS UK LTD

4.2.1 Boots UK Ltd do not believe the Applicant has provided any evidence to suggest patients in this locality are having difficulty accessing existing provision. They have not provided any indication that patients who share a protected characteristic do not have access to services to meet any specific needs that would be met by the granting of this application.

4.2.2 The appeal is based on the offer of providing pharmaceutical provision on Christmas Day and Easter Sunday, which the Applicant believes to be an “innovative unforeseen benefit”.

4.2.3 With regard to access on Christmas Day and Easter Sunday, Schedule 4, Part 3, Regulation 23(12) states: For the purposes of calculating the number of hours that pharmacy premises are open during a week that includes Christmas Day, Good Friday, Easter Sunday or a bank holiday, it is to be deemed that the pharmacy premises were open on that day at the times at which they would ordinarily have been open on that day of the week.

4.2.4 The Pharmacy Manual states: Contractors are not required to open on public (Christmas Day and Good Friday) or bank holidays (including any specially declared bank holidays). In addition, they are not required to open on Easter Sunday, which is neither a public nor bank holiday. They are encouraged to notify NHS England well in advance so that consideration can be given as to whether the provision of pharmaceutical services on these days will meet the reasonable needs of patients and members of the public.

4.2.5 Boots UK Ltd do not believe that the Applicant has provided any evidence of innovation in their appeal. Boots UK Ltd therefore request that NHS Resolution dismiss this appeal.

4.2.6 Boots UK Ltd have enclosed a copy of their original response to NHS England for [your] consideration.

4.2.7 Please be aware that Boots UK Ltd may wish to attend any Oral Hearing that may be required in connection with this application.

In a letter dated 11 March 2020 to NHS England, Boots UK Ltd stated:

4.2.8 The applicant has not provided any evidence of the residents in Uckfield experiencing difficulties when accessing pharmaceutical provision in this locality, services nor has the applicant provided any indication that patients who share a protected characteristic do not have access to services to meet any specific needs.

- 4.2.9 There are four pharmacies within a mile of the proposed location. Boots UK Ltd's pharmacy at 11 High Street, Uckfield is located approximately 250 metres (0.1 mile) from the application site. Boots UK Ltd are not aware of any patients having difficulty accessing their pharmacy. Extended hours provision is provided by Tesco who are open 78 hours a week and are located 0.3 miles away.
- 4.2.10 Furthermore, there is no evidence to suggest patients do not currently have access to a reasonable choice of pharmaceutical services or that the application is based on innovative approaches to the delivery of pharmaceutical services. By the applicants own submission, in section 6 they state that "On most days, the pharmaceutical service in Uckfield is adequate."
- 4.2.11 With regard to access on Christmas Day and Easter Sunday, Schedule 4, Part 3, Regulation 23(12) states: For the purposes of calculating the number of hours that pharmacy premises are open during a week that includes Christmas Day, Good Friday, Easter Sunday or a bank holiday, it is to be deemed that the pharmacy premises were open on that day at the times at which they would ordinarily have been open on that day of the week.
- 4.2.12 The Pharmacy Manual states: Contractors are not required to open on public (Christmas Day and Good Friday) or bank holidays (including any specially declared bank holidays). In addition, they are not required to open on Easter Sunday, which is neither a public nor bank holiday. They are encouraged to notify NHS England well in advance so that consideration can be given as to whether the provision of pharmaceutical services on these days will meet the reasonable needs of patients and members of the public.
- 4.2.13 With this in mind, there should not be a gap in pharmaceutical provision at such times that would warrant the need for an additional pharmacy in this locality.
- 4.2.14 In conclusion Boots UK Ltd submit that the application should be refused as it will not confer significant benefits on persons in the area of the relevant Health and Wellbeing Board which were not foreseen when the relevant Pharmaceutical Needs Assessment was published.
- 4.2.15 Please be aware that Boots UK Ltd may wish to make further representations at a later stage and attend any oral hearing that may be held.

5 Observations

No observations were received by NHS Resolution in response to the representations received on appeal.

6 Consideration

- 6.1 The Pharmacy Appeals Committee ("the Committee"), appointed by NHS Resolution, had before it the papers considered by NHS England, together with a plan of the area showing existing pharmacies and doctors' surgeries and the location of the proposed pharmacy.
- 6.2 It also had before it the responses to NHS Resolution's own statutory consultations.
- 6.3 On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.
- 6.4 The Committee had regard to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations").

Regulation 31

6.5 The Committee first considered Regulation 31 of the Regulations which states:

(1) A routine or excepted application, other than a consolidation application, must be refused where paragraph (2) applies.

(2) This paragraph applies where -

(a) a person on the pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services ("the existing services") from -

(i) the premises to which the application relates, or

(ii) adjacent premises; and

(b) the NHSCB is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the same service as the existing services (and so the premises to which the application relates and the existing listed chemist premises should be treated as the same site).

6.6 The Committee noted 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 was not met and further that no party has sought to argue this point on appeal. The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 18

6.7 The Committee noted that this was an application for "unforeseen benefits" and fell to be considered under the provisions of Regulation 18 which states:

"(1) If—

(a) the NHSCB receives a routine application and is required to determine whether it is satisfied that granting the application, or granting it in respect of some only of the services specified in it, would secure improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and

(b) the improvements or better access that would be secured were or was not included in the relevant pharmaceutical needs assessment in accordance with paragraph 4 of Schedule 1,

in determining whether it is satisfied as mentioned in section 129(2A) of the 2006 Act (regulations as to pharmaceutical services), the NHSCB must have regard to the matters set out in paragraph (2).

(2) Those matters are—

- (a) *whether it is satisfied that granting the application would cause significant detriment to—*
- (i) *proper planning in respect of the provision of pharmaceutical services in the area of the relevant HWB, or*
 - (ii) *the arrangements the NHSCB has in place for the provision of pharmaceutical services in that area;*
- (b) *whether, notwithstanding that the improvements or better access were not included in the relevant pharmaceutical needs assessment, it is satisfied that, having regard in particular to the desirability of—*
- (i) *there being a reasonable choice with regard to obtaining pharmaceutical services in the area of the relevant HWB (taking into account also the NHSCB's duties under sections 13I and 13P of the 2006 Act (duty as to patient choice and duty as respects variation in provision of health services)),*
 - (ii) *people who share a protected characteristic having access to services that meet specific needs for pharmaceutical services that, in the area of the relevant HWB, are difficult for them to access (taking into account also the NHSCB's duties under section 13G of the 2006 Act (duty as to reducing inequalities)), or*
 - (iii) *there being innovative approaches taken with regard to the delivery of pharmaceutical services (taking into account also the NHSCB's duties under section 13K of the 2006 Act (duty to promote innovation)),*
- granting the application would confer significant benefits on persons in the area of the relevant HWB which were not foreseen when the relevant pharmaceutical needs assessment was published;*
- (c) *whether it is satisfied that it would be desirable to consider, at the same time as the applicant's application, applications from other persons offering to secure the improvements or better access that the applicant is offering to secure;*
- (d) *whether it is satisfied that another application offering to secure the improvements or better access has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;*
- (e) *whether it is satisfied that an appeal relating to another application offering to secure the improvements or better access is pending, and it would be desirable to await the outcome of that appeal before considering the applicant's application;*
- (f) *whether the application needs to be deferred or refused by virtue of any provision of Part 5 to 7.*
- (g) *whether it is satisfied that the application presupposes that a gap in pharmaceutical services provision has been or is to be created—*
- (i) *by the removal of chemist premises from a pharmaceutical list as a consequence of the grant of a consolidation application, and*

(ii) *since the last revision of the relevant HWB's pharmaceutical needs assessment other than by way of a supplementary statement.*

(3) *The NHSCB need only consider whether it is satisfied in accordance with paragraphs (2)(c) to (e) if it has reached at least a preliminary view (although this may change) that it is satisfied in accordance with paragraph (2)(b)."*

6.8 The Committee considered that Regulation 18(1)(a) was satisfied in that it was required to determine whether it was satisfied that granting the application, or granting it in respect of some only of the services specified in it, would secure improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB

6.9 The Committee went on to consider whether Regulation 18(1)(b) was satisfied, i.e. whether the improvements or better access that would be secured if the application was granted were or was included in the PNA in accordance with paragraph 4 of Schedule 1 of the Regulations.

6.10 Paragraph 4 of Schedule 1 requires the PNA to include: *"a statement of the pharmaceutical services that the HWB had identified (if it has) as services that are not provided in the area of the HWB but which the HWB is satisfied (a) **would** if they were provided....secure improvements or better access, to pharmaceutical services... (b) **would** if in specified future circumstances they were provided...secure future improvements or better access to pharmaceutical services..."* (emphasis added).

6.11 The Committee considered the Pharmaceutical Needs Assessment ("the PNA") prepared by East Sussex County Council, conscious that the document provides an analysis of the situation as it was assessed at the date of publication. The Committee bears in mind that, under regulation 6(2), the body responsible for the PNA must make a revised assessment as soon as reasonably practicable (after identifying changes that have occurred that are relevant to the granting of applications) unless to do so appears to be a disproportionate response to those changes. Where it appears disproportionate, the responsible body may, but is not obliged to, issue a Supplementary Statement under regulation 6(3). Such a statement then forms part of the PNA. The Committee noted that the PNA was dated July 2017 and that no supplementary statements had been issued.

6.12 The Committee noted that there are 2 boroughs in East Sussex and 3 districts. The PNA had looked at the areas covered by the three CCGs in East Sussex and that Uckfield fell within Wealden district which is in the High Weald Lewes Havens CCG. The Committee noted that the PNA had looked at the three CCGs and had also reviewed the districts as a whole but had not considered individual areas within either the districts or the CCGs.

6.13 The Committee noted that the PNA had considered the ease of access to a pharmacy and had concluded, in Section 10 'Conclusions and recommendations' that:

"Where people have access to a car there is adequate access in terms of travel times to a pharmacy in all parts of the county, including weekends. Over a third of pensioner households do not have access to a car, however. The proportion not having access to a car varies by local authority.

By public transport (two way journeys) there are rural areas mainly in Wealden and Rother during the day with no access. There are even larger areas of the county with no access to a pharmacy by public transport on weekday evenings and on Saturdays and Sundays, particularly in the Hailsham area.

For people who are unable to afford any public transport (and can only access a pharmacy by walking) there is only reasonable access in urban areas."

6.14 And further

"In summary, the current level of access to NHS pharmaceutical services is adequate for those who own a car, or live in urban areas. There are larger areas of the county with no access to a pharmacy by public transport on weekday evenings and on Saturdays and Sundays, particularly in the Wealden (Hailsham) area."

6.15 The Committee noted that the findings from the PNA showed that *"Overall, however, there is good service pharmaceutical provision across East Sussex. Where the area is rural there are enough dispensing practices to provide essential dispensing services to the rural population. There are areas where population may increase due to housing development, however this may not affect pharmaceutical service provision within the lifetime of this PNA."*

6.16 The Committee noted that the Applicant seeks to provide unforeseen benefits to those who reside in Uckfield. The Committee noted that the improvements or better access that the Applicant was claiming would be secured by its application were not included in the relevant pharmaceutical needs assessment in accordance with paragraph 4 of Schedule 1.

6.17 In order to be satisfied in accordance with Regulation 18(1), regard is to be had to those matters set out at 18(2). The Committee's consideration of the issues is set out below.

Regulation 18(2)(a)(i)

6.18 The Committee had regard to

"(a) whether it is satisfied that granting the application would cause significant detriment to—

(i) proper planning in respect of the provision of pharmaceutical services in the area of the relevant HWB"

6.19 The Committee noted that NHS England had concluded that they were not aware of any plans that would be affected and concluded that the granting of the application would not have an adverse effect on future plans. The Committee noted that no party had sought to argue or produce any information which would support a finding that significant detriment would be caused if the application was granted.

6.20 On the basis of the information available, the Committee was not satisfied that, if the application were to be granted and the pharmacy to open, the ability of the NHS England thereafter to plan for the provision of services would be affected in a significant way.

6.21 The Committee was therefore not satisfied that significant detriment to the proper planning of pharmaceutical services would result from a grant of the application.

Regulation 18(2)(a)(ii)

6.22 The Committee had regard to

"(a) whether it is satisfied that granting the application would cause significant detriment to— ...

(ii) the arrangements the NHSCB has in place for the provision of pharmaceutical services in that area"

6.23 The Committee noted that NHS England had not found that there would be significant detriment to the arrangements in place for the provision of pharmaceutical services if

the application was to be granted. The Committee noted that no party had sought to argue or produce any information which would support a finding that significant detriment would be caused. On the basis of the information available, the Committee was therefore not satisfied that significant detriment to the arrangements currently in place for the provision of pharmaceutical services would result from a grant of the application.

- 6.24 In the absence of any significant detriment as described in Regulation 18(2)(a), the Committee was not obliged to refuse the application and went on to consider Regulation 18(2)(b).

Regulation 18(2)(b)

- 6.25 The Committee had regard to

"(b) whether, notwithstanding that the improvements or better access were not included in the relevant pharmaceutical needs assessment, it is satisfied that, having regard in particular to the desirability of—

(i) there being a reasonable choice with regard to obtaining pharmaceutical services in the area of the relevant HWB (taking into account also the NHSCB's duties under sections 13I and 13P of the 2006 Act (duty as to patient choice and duty as respects variation in provision of health services)),

(ii) people who share a protected characteristic having access to services that meet specific needs for pharmaceutical services that, in the area of the relevant HWB, are difficult for them to access (taking into account also the NHSCB's duties under section 13G of the 2006 Act (duty as to reducing inequalities)), or

(iii) there being innovative approaches taken with regard to the delivery of pharmaceutical services (taking into account also the NHSCB's duties under section 13K of the 2006 Act (duty to promote innovation)),

granting the application would confer significant benefits on persons in the area of the relevant HWB which were not foreseen when the relevant pharmaceutical needs assessment was published"

Regulation 18(2)(b)(i) to (iii)

- 6.26 The Committee had regard to the location of the existing pharmacies and GP surgeries as provided on the map by NHS England which had not been disputed by any party. The Committee further noted the undisputed comments that there are 3 pharmacies within 0.6 km of the proposed site, which are operated by different contractors.

- 6.27 The Committee noted that the Applicant had not argued that access on foot was not reasonable due to physical or geographic barriers.

- 6.28 Indeed, the Committee noted the comment from the Applicant that "on most days, the pharmaceutical service in Uckfield is adequate". The Committee noted the comments from the Applicant that bus services are minimal during the week but that on Easter Sunday and Christmas Day there are no bus services or other public transport services. The Committee noted that the Applicant had made reference to the PNA and had highlighted that there were areas of the county, particularly in the Wealden (Hailsham) area that had limited public transport. The Committee noted however that the PNA had made reference to this with particular regard to travelling and access to pharmaceutical services on a Sunday. The Committee noted that the Applicant was not seeking to offer any provision on a Sunday. The Committee noted that the minimal bus services during the week had been disputed and that NHS England had concluded that bus

services in the area were good and that this had not been disputed by the Applicant on appeal. The Committee further noted that the PNA had concluded that the areas with poor public transport were the rural areas and noted that no information had been provided by the Applicant to demonstrate that the location of the proposed pharmacy was in a rural area.

- 6.29 With regard to access by private transport, the Committee noted the reference to the PNA from the Applicant that 27.7% of pensioner households do not have a car, but noted that this had not been expanded upon and no further information had been provided to demonstrate that those who did have access to private transport were having difficulties in accessing pharmaceutical services. The Committee noted the undisputed comments from NHS England that there was ample parking at the Tesco pharmacy. The Committee noted the comments from the Applicant with regard to access to pharmaceutical services on Christmas Day and Easter Sunday, which the Applicant states are the days when access is hardest, but there was no information provided to demonstrate that those who did require services on these 2 days had experienced any difficulties in accessing pharmaceutical services from the existing provision.
- 6.30 The Committee, whilst noting the statement from the Applicant with regard to car ownership, noted that there was nothing provided to demonstrate that those who did not have access to private transport and chose to access existing pharmaceutical services on foot were experiencing any difficulties in accessing the existing pharmaceutical provision. In conclusion, the Committee was of the view that for those who access pharmaceutical services on foot, by car or public transport there was nothing provided to demonstrate that they were experiencing any difficulties in accessing the existing pharmaceutical provision.
- 6.31 The Committee noted that the Applicant was seeking the inclusion on the basis of securing improvements or better access to opening hours on Easter Sunday and Christmas Day. The Committee noted the comments from Boots and references to the Regulations and the Pharmacy Manual with regard to the provision of pharmaceutical services on the days in question. The Committee noted that the existing rota system provides 4 hours of cover on the days in question whilst the Applicant was offering to provide 3 hours of cover. The Committee was of the view that there is already a rota system in place and that NHS England are able to direct existing pharmacies, including the pharmacies that the Application already operates in Uckfield, to open for specific hours if a need was identified.
- 6.32 The Committee also noted that the Applicant was proposing to open for a total of 53 hours a week, all of which the Applicant had declared as core hours. The Committee was mindful that any hours over the standard 40 core hours would have to be directed and agreed with NHS England. The Committee noted that the Applicant had given the hours as 9am to 6pm Monday to Friday and 9am to 5pm on a Saturday and had not stated which of these hours would be the directed 13 hours, if the application was to be granted. The Committee noted that the Applicant was not proposing to offer any hours, core, directed or supplementary on a Sunday. The Committee noted that the Tesco pharmacy was already providing extended opening hours and that there was nothing provided by the Applicant to demonstrate that the hours currently offered by existing providers were not sufficient which led to a gap in provision which this pharmacy would secure. The Committee was of the view that there was no information provided to support a finding that pharmaceutical services are not currently provided at such times as needed.
- 6.33 On the information before it, the Committee was of the view that there is already reasonable choice with regard to obtaining pharmaceutical services in the area of the relevant HWB, such that it was not satisfied that, having regard to the desirability of there being a reasonable choice with regard to obtaining services, granting the application would confer significant benefits on persons.

- 6.34 In considering Regulation 18(2)(b)(ii) the Committee reminded itself that it was required to address itself to people who share a protected characteristic having access to services that meet specific needs for pharmaceutical services that are difficult for them to access. The Committee was also aware of its duties under the Equality Act 2010 which include considering the elimination of discrimination and advancement of equality between patients who share protected characteristics and those without such characteristics. The Committee noted the statements from the Applicant with regard to the pensioner households in the area, however the Committee noted that this had not been expanded upon. The Committee accepted that there would always be those in an area who shared a protected characteristic, however there was nothing provided by the Applicant as to why the granting of this application would lead to a significant benefit or how those with a protected characteristic were currently experiencing any difficulties in accessing pharmaceutical services. The Committee was therefore not satisfied that, having regard to the desirability of people who share a protected characteristic having access to services that meet specific needs for pharmaceutical services that are difficult for them to access, granting the application would confer significant benefits on persons.
- 6.35 In considering Regulation 18(2)(b)(iii) the Committee had regard to the desirability of innovative approaches to the delivery of pharmaceutical services. In doing so, the Committee would consider whether there was something more over and above the usual delivery of pharmaceutical services that might be expected from all pharmacies, some 'added value' on offer at the location.
- 6.36 The Committee noted that the comments from the Applicant that the application provides two innovative approaches in that they would be offering guaranteed hours on both Christmas Day and Easter Sunday as well as offering a delivery service on both of these days for anyone who needed to access pharmaceutical services.
- 6.37 The Committee was of the view that providing hours on both Christmas Day and Easter Sunday, whilst commendable, was not an innovative service given that there is already a rota system in place and that NHS England are able to direct existing pharmacies, including the pharmacies that the Application already operates in Uckfield, to open for specific hours if a need was identified.
- 6.38 The Committee further noted that the second service proposed by the Applicant was to offer a free of charge delivery service during the proposed opening hours on both Easter Sunday and Christmas Day. The Committee was mindful that a collection and delivery service, irrespective of the day that it is to be provided, is not an innovative service. Further, the Committee was mindful that the Applicant could offer this service from their existing pharmacies if either of these was included on the rota for the provision of pharmaceutical services on either Christmas Day, Easter Sunday or any other bank holiday.
- 6.39 The Committee was not satisfied that, having regard to the desirability of there being innovative approaches taken with regard to the deliverability of pharmaceutical services, granting the application would confer significant benefits on persons.

Regulation 18(2)(b) generally

- 6.40 The Committee was of the view that in accordance with Regulation 18(2)(b) the granting of this application would not confer significant benefits on persons in the area of the HWB which were not foreseen when the PNA was published.

Other considerations

- 6.41 Having determined that Regulation 18(2)(b) had not been satisfied, the Committee did not need to have regard to Regulation 18(2)(c) to (e).
- 6.42 No deferral or refusal under Regulation 18(2)(f) was required in this case.

- 6.43 The Committee considered whether there were any further factors to be taken into account and concluded that there were not.
- 6.44 The Committee was not satisfied that the information provided demonstrates that there is difficulty in accessing current pharmaceutical services such that a pharmacy at the proposed site would provide better access to pharmaceutical services.
- 6.45 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:
- 6.45.1 confirm NHS England's decision;
 - 6.45.2 quash NHS England's decision and redetermine the application;
 - 6.45.3 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.
- 6.46 In those circumstances, given the further findings of the Committee in respect of innovation, the Committee determined that the decision of NHS England must be quashed.
- 6.47 The Committee went on to consider 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 remit the matter to NHS England) or whether it was preferable for the Committee to redetermine the application.
- 6.48 The Committee noted that representations on Regulation 18 had been sought from parties by NHS England and representations had already been made by parties to NHS England in response. 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 18.
- 6.49 The Committee concluded that further notification under paragraph 19 of Schedule 2 would not be helpful in this case.

7 DECISION

- 7.1 The Pharmacy Appeals Committee ("Committee"), appointed by NHS Resolution, quashes the decision of NHS England, for the reasons given above, and redetermines the application.
- 7.2 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.
- 7.3 The Committee has considered whether the granting of the application would cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the area covered by the HWB, or the arrangements in place for the provision of pharmaceutical services in that area and is not satisfied that it would;
- 7.4 The Committee determined that the application should be refused on the following basis:
- 7.4.1 In considering whether the granting of the application would confer significant benefits, the Committee determined that –
 - 7.4.1.1 there is already a reasonable choice with regard to obtaining pharmaceutical services;

- 7.4.1.2 there is no evidence of people sharing a protected characteristic having difficulty in accessing pharmaceutical services; and
- 7.4.1.3 there is no evidence that innovative approaches would be taken with regard to the delivery of pharmaceutical services;
- 7.4.2 Having taken these matters into account, the Committee is not satisfied that granting the application would confer significant benefits as outlined above that would secure improvements or better access to pharmaceutical services.

**Case Manager
Primary Care Appeals**

A copy of this decision is being sent to:

Waremass Ltd
Boots UK Ltd
PCSE on behalf of NHS England – South East Area Team