

**NHS England South East (Thames Valley)
Pharmaceutical Services Regulations Committee**

Annex 6.1 to the minutes of the meeting held on Wednesday 27th January 2021

Agenda Item 6.1	ACTION
<p>6.1 Minerva Clinical Services Ltd – Unforeseen benefits</p> <ul style="list-style-type: none"> • CAS-3045085-J9D6K1 • Retail Units at Heyford Park Village Centre, The Station House, Camp Road, OX25 5BZ • Oxfordshire HWB <p>1. Introduction and background</p> <p>1.1 An unforeseen benefits application had been received from Minerva Clinical Services Ltd, on 27th July 2020. 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.</p> <p>1.2 Full details of the applicant’s proposal had been notified to the various interested parties in accordance with the regulations. Comments had been received from the following: Superdrug Stores Plc, Boots UK Ltd, Lloyds Pharmacy Ltd, Jardines (UK) Ltd, Montgomery House Surgery, Chalice Pharmacies Ltd and Thames Valley LPC. There were also follow up comments from the applicant.</p> <p>2. Consideration by the Committee</p> <p>2.1 The Committee had before it:</p> <p>2.1.1 The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.</p> <p>2.1.2 Department of Health guidelines on market entry by means of pharmaceutical needs assessment – Chapter 8 – Unforeseen Benefits.</p> <p>2.1.3 Department of Health guidance on Market Entry by means of pharmaceutical needs assessment – Chapter 14 – provision of pharmaceutical services in controlled localities</p> <p>2.1.4 The Report and annexes prepared by Primary Care Support England (PCSE) and NHS England:</p> <p>2.1.5 The application form provided by the applicant.</p> <p>2.1.6 The Committee noted that the applicant’s fitness to practise was approved by NHS England South East on 11th September 2020.</p>	



<p>2.1.7</p> <p>2.1.8</p> <p>2.1.9</p> <p>2.1.10</p> <p>2.1.11</p> <p>2.1.12</p> <p>2.1.13</p> <p>2.2</p>	<p>It was noted that the applicant's best estimate had been previously agreed.</p> <p>The Committee noted that the applicant was proposing to provide essential, enhanced and advanced services, if commissioned.</p> <p>The applicant also proposed core opening of 40 hours per week and total proposed opening of 48 hours per week.</p> <p>The Committee considered the applicant's statement as to the unforeseen benefits it is offering. The Applicant has stated that <i>"The closest existing pharmacies to Upper Heyford are a considerable distance away. To the north west is a Delmergate Pharmacy situated in the town of Deddington. This pharmacy is 6 miles from Upper Heyford.</i></p> <p><i>To the South East lies the town of Bicester with the nearest pharmacies between 7 and 8 miles from Upper Heyford.</i></p> <p><i>Accessing these pharmacies present serious difficulty to patients. There is no public transport option from Upper Heyford to Deddington even through it is the nearest pharmacy. The only way to access the pharmacy in Deddington by public transport is to travel south, well past Bicester and then go back north from Oxford. The journey time is approximately 1.5 to 2 hours each way."</i></p> <p>The application stated <i>"Given the distances involved, walking is not an option for patients and that only leaves patients with a car who can claim to have better access. However, Upper Heyford and Heyford Park is designed to be inward looking for most of its day to day needs and indeed, it attracts people to the area. It therefore cannot simply be assumed that patients would be working elsewhere in areas where there may (or may Not) be a pharmacy."</i></p> <p>The application also stated <i>"Unfortunately the available census statistics are of little help given that they do not include and of the significant new development and are nearly 10 years old, whereas the deprivation statistics quoted above are from 2019. In any event, this application is not made due to deprivation, but because of significant growth across residential, retail and commercial activities and the requirement to provide healthcare services as part of the NHS System of care."</i></p> <p>The information submitted by the Applicant along with the application indicates that the Applicant proposes to provide pharmaceutical services to the residents of Heyford Park from the best estimate location. The applicant has not made any reference to Oxfordshire PNA in their Application"</p> <p>All additional information, including location, opening times and distances of surrounding pharmacies and GP Surgeries were noted and considered by the Committee.</p>	
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- 2.3 The Committee considered the representations made by Superdrug Stores Plc, Boots UK Ltd, Lloyds Pharmacy Ltd, Jardines (UK) Ltd, Montgomery House Surgery, Chalice Pharmacies Ltd and Thames Valley LPC – and noted the comments made by the interested parties. The Committee noted that Jardines (UK) Ltd, Montgomery House Surgery, Chalice Pharmacies Ltd and Thames Valley LPC opposed the application.
- 2.4 The Committee also noted the unsolicited comment received from Steeple Aston Parish Council and the Mid Cherwell Neighbourhood Plan Forum.
- 2.5 The applicant’s response to the representations received during the consultation period was also considered.

3. Regulation 31 – Refusal: same or adjacent premises

- 3.1 The Committee first 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.
- 3.2 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.
- 3.3 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.

4. Regulations 40,41 and 44

- 4.1 The Committee noted that the proposed pharmacy location was in a controlled locality, and therefore Part 7 of the Regulations (in particular Regulations 40, 41 and 44) were to be considered.
- 4.2 **Regulation 40 – Application for new pharmacy premises in controlled localities: refusal because of preliminary matters** – the Committee was aware that no application has been refused within the controlled locality, nor has outline consent for GP dispensing been granted within five years of receipt of this application. There was therefore no need to refuse the application under Regulation 40.
- 4.3 **Regulation 41 – Applications for new pharmacy premises in controlled localities: reserved locations** – The Committee noted that the number of registered patients within 1.6km of the best estimate address was 2,358. The Committee further noted that interested parties had been informed that NHS England is required to make a determination on whether the location of the proposed pharmacy is in a reserved location as defined in regulation 41(3). None of the representations received contained any statement disputing the figures nor were any particular arguments made regarding the possibility that the area might or might not be a reserved location.



- 4.4 As the figure was below the 2,750-threshold figure, the Committee determined that the area was a reserved location, and therefore was not required to consider Regulation 44.
- 4.5 The Committee also noted there were no comments made regarding any potential adverse impact an approval of the application would have on a local GP Practice, including a loss of income to the practice and a potential reduction in the medical services currently provided.
- 4.6 Having considered the representations, the Committee was not satisfied that granting the application would, in its opinion, prejudice the proper provision of relevant NHS services in the Heyford Park area. The Committee was therefore not required to refuse the application under regulation 41.
- 4.7 There are 1,885 dispensing patients living within 1.6km radius of the proposed best estimate address. The Committee noted that as the area was a reserved location it would not be required to consider the discontinuation of arrangements for the provision of pharmaceutical services by doctors to the affected patients under Regulation 50.

5. Oral Hearing

- 5.1 The Committee decided that it was not necessary to hold an oral hearing before determining the application.

6. Regulation 18 – Unforeseen benefits application

- 6.1 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).*
- 6.2 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

<p>6.3</p> <p>6.4</p> <p>6.5</p> <p>6.6</p> <p>6.7</p> <p>6.8</p> <p>6.9</p> <p>6.10</p> <p>6.11</p>	<p>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 Pharmaceutical Needs (the 'PNA') in accordance with paragraph 4 of Schedule 1 of the Regulations.</p> <p>The Committee had regard to the Oxfordshire PNA 2018 (issue date 31st March 2018) (the 'PNA') and noted that supplementary statements had been issued on 20/09/2018 and 20/06/2019 but were/were not in relation to the Heyford Park area.</p> <p>The Committee noted that the Health and Wellbeing Board ('HWB') had commissioned an assessment of the current capacity of pharmacies in the areas of known housing growth within Oxfordshire and had reached the conclusion that;</p> <p><i>“Whilst there is no requirement for any new pharmacy premises to provide essential services, there are opportunities available to maximise existing and future services. Pharmaceutical services available are described within the document; additionally, information on services at each pharmacy and opening hours are available through NHS Choices.”</i> [Page 79, Oxfordshire PNA, 2018]</p> <p>The Committee also noted that, having considered the entire Oxfordshire locality including the area of Upper Heyford, the HWB had stated that <i>“There is a need to provide improvements and better access for the population of Caversfield, Upper Heyford, Berinsfield, Hanborough and Shipton-under-Wychwood.”</i> [Page 79, Oxfordshire PNA, 2018]</p> <p>The PNA in its conclusion also states <i>“Based on the information available at the time of developing the PNA, no gaps in pharmaceutical service provision were identified and there is no need for further premises. However, there are opportunities for improvements or better access in some areas: Planned housing developments in Caversfield and Upper Heyford mean that an increased number of residents may have to travel further to access essential services.”</i> [Page 79, Oxfordshire PNA, 2018]</p> <p>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.</p> <p>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.</p> <p>The Committee was satisfied that a gap was not identified in the lifetime of the PNA.</p> <p>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).</p>	
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- 6.12 **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.*
- 6.13 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. None of the submissions included any comment or evidence in regard to this matter. Therefore, the Committee concluded that granting the application would not cause significant detriment in this regard.
- 6.14 **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.*
- 6.15 None of the submissions included any evidence on this question and the Committee found no proof to support the suggestion that if the application was to be granted, it would cause significant detriment to the arrangements in place for pharmaceutical services in the area.
- 6.16 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).
- 6.17 **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.*
- 6.18 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 Heyford Park area.
- 6.19 The Committee noted that the village of Heyford Park lies 7.5 miles South East of Bicester. There is no pharmacy provision in the village; however there are 8 pharmacies within 5 miles of Heyford Park by road which could be access in less than 20 minutes' drive, the Committee noted that the distances to the nearby pharmacies were not unreasonable in the context of a rural area.
- 6.20 The Committee had regard to the current service provision in the immediate area of Heyford Park and noted that there are 8 pharmacies within 5-mile radius of the best estimate address, the opening hours of the five pharmacies range from 08:00 to 23:00 on Mondays, 07:00-23:00 Tuesday to Saturday. Sunday opening hours range from 09:00 to 19:00
- 6.21 The Committee noted that the Applicant had offered to open from 09:00 to 18:00 on Monday to Friday, Saturday opening of 09:00 to 12:00 and



closed on Sundays. However, there were already pharmacies within 5 miles providing longer hours on all days of the week.

- 6.22 Heyford Park offers limited services, so it is likely that residents will have to travel outside the village to access various services.
- 6.23 The Committee also noted that patients in the area of Heyford also had a reasonable choice as to which providers from which to access pharmaceutical services. Including 2 Lloyds Pharmacies, Boots Pharmacy, Superdrug Pharmacy and four independently run pharmacies.
- 6.24 Having considered the factors above, the Committee was satisfied that residents of Heyford Park already have reasonable choice with regard to obtaining pharmaceutical services in the area of the Health and Wellbeing Board.
- 6.25 **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.*
- 6.26 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 Quality Act 2010 which include considering the elimination of discrimination and advancement of equality between patients who share protected characteristics and those within such characteristics.
- 6.27 The Committee received no evidence that identified a group of patients in the Heyford Park area, sharing a protected characteristic with difficulty accessing services that meet a specific need.
- 6.28 The Committee therefore concluded that the application did not satisfy the test in this part of the Regulation.
- 6.29 **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.*
- 6.30 The Application under the heading “Providing Additional Primary Care Services / Innovation” states;

“My Client’s proposal goes much further than providing pharmaceutical services and will deliver those services and will deliver those services in innovative ways. The Applicant company, Minerva Clinical Services Limited, is linked to the Alchester Group Medical Practice partners.



As part of this proposal, the new pharmacy will provide rooms for the Alchester Group Medical Practice to provide GP appointments on site alongside them at Heyford Park. In addition to providing the services required under GP contract, the doctors will support the pharmacy team by offering enhanced support for self-care and being involved in services such as the New Medicines Service. Instead of a pharmacy seeking to co-locate with a GP practice, this application offers the opportunity to secure not only pharmaceutical service for the area but also primary medical services which support the provision of the pharmaceutical services. Doctors will support the new pharmacy team whilst always recognising a patient's right to choose where they access services and which pharmacy they use.

The Pharmacy will operate a triage and advice system which includes access to a GP, compared to existing models which are inevitable operated in reverse.”

6.31 The Committee noted these comments made in the application but were in agreement that these were not an innovative approach to the provision of pharmaceutical services, as they were around the provision of primary medical care delivered by the GPs.

6.32 Committee agreed that the applicant had not provided evidence that an innovative approach would be taken with regard to the delivery of pharmaceutical services.

6.33 Therefore, the Committee concluded that there is no evidence that innovative approaches would be taken with regard to the delivery of pharmaceutical services.

6.34 Other Considerations

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).

7. Decision

7.1 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.

7.2 The Committee had 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.

7.3 The Committee determined that the application should be Refused on the following basis:

7.3.1 In considering whether the granting of the application would confer significant benefits, the Committee determined that –

- there is already a reasonable choice with regard to obtaining pharmaceutical services;
- there is no evidence of people sharing a protected characteristic having difficulty in accessing pharmaceutical services; and
- there is no evidence that innovative approaches would be taken with regard to the delivery of pharmaceutical services.

7.4 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.

8. Rights of appeal

8.1 The application is refused so the applicant has the right to appeal.

8.2 The Committee decided not to grant third party rights of appeal to the decision of NHS England and Improvement to any of the parties that responded during the consultation period because the application had been refused.

