

15 January 2024

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10 South Colonnade
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FILE REF: SHA/26074

Tel: 0203 928 2000
Email: nhsr.appeals@nhs.net

DECISION MAKING BODY: NHS SOUTH WEST (“the Commissioner”)

PHARMACIST: Clarepharm Ltd (“the Applicant”)

PREMISES: WESCOTT MILL
65 NEW STREET
HONITON
DEVON
EX14 1BX

**THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL AND LOCAL
PHARMACEUTICAL SERVICES) REGULATIONS 2013 [“THE REGULATIONS”]**

**SCHEDULE 4 [Terms of Service of NHS Pharmacists]
PART 3 [Hours of Opening]**

Outcome

- 1.1 I consider that, on the basis of the information provided to me, it is necessary to maintain the existing level of service provision and that not enough information has been provided for me to consider that maintaining the existing level of service provision is not a realistically achievable outcome. Although this leaves an undesirable situation, where the Applicant continues to provide 44 core opening hours without a direction being in place, I consider the lack of information does not enable me acting reasonably to make a determination of the days and times of the 40 core opening hours.
- 1.2 I consider that the only option open to me is therefore to confirm the action taken by the Commissioner to refuse the application.

A copy of this decision is being sent to:

Pharmacy Sales & Consultancy, on behalf of Clarepharm Ltd
NHS South West Collaborative Commissioning Hub

Advise / Resolve / Learn

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PART 3 [Hours of Opening]**

1 Introduction

- 1.1 The Applicant has applied to the Commissioner to change the days and times at which it is obliged to provide pharmaceutical services at the above premises. The Applicant seeks to reduce the total number of core opening hours.
- 1.2 The Commissioner has refused the application. The Applicant seeks to appeal to NHS Resolution.

2. Consideration

Rights of appeal

- 2.1 Where the Commissioner has determined an application under paragraph 26 of Schedule 4 of the Regulations and has granted it in part only or has taken an action that has the effect of refusing it, paragraph 26(9) provides a right of appeal to the Secretary of State for Health and Social Care (“the Secretary of State”).
- 2.2 The Secretary of State has directed NHS Resolution to determine such appeals. As an authorised officer of NHS Resolution, I have considered the appeal and have determined it, in accordance with my delegated powers.

Opening hours

2.3 A pharmacy's opening hours may be categorised as:

- 2.3.1 “core opening hours” (at the hours during which the pharmacy must be open by virtue of paragraph 23(1) of Schedule 4 of the Regulations), which may incorporate a direction of the Commissioner requiring fewer or greater than 40 hours and at set times and days; or
- 2.3.2 “supplementary” opening hours (other hours during which the pharmacy premises are open which are in addition to the core hours), pursuant to paragraph 23(3) of Schedule 4 of the Regulations.

Alteration of core opening hours

2.4 In accordance with paragraphs 1(7)(c) and 1(7)(d) of Schedule 2 of the Regulations, the pharmacy must provide, as part of an application for entry in the pharmaceutical list:

- 2.4.1 the proposed core opening hours in respect of the premises; and
- 2.4.2 the total proposed opening hours for the premises (having regard to both the proposed core opening hours and any supplementary opening hours).

2.5 The Commissioner maintains pharmaceutical lists that include the days on which and times at which, at those premises, the listed person is to provide those services during the core opening hours and any supplementary opening hours of the premises.

2.6 The days on which or times at which a pharmacy is obliged to provide pharmaceutical services at the premises may only be altered by the pharmacy on application under paragraph 26(1) of Schedule 4 of the Regulations, so long as the effect of that application is to reduce the total number of hours for which a pharmacy is obliged to provide, or keep the total number of hours the same.

Alteration of supplementary opening hours

2.7 Supplementary opening hours may be altered by the pharmacy giving notice to the Commissioner, in accordance with paragraph 23(6)(a) of Schedule 4 of the Regulations, without the need to make an application to the Commissioner.

2.8 There is no specific right of appeal to NHS Resolution in respect of notices given under paragraph 23(6)(a).

Clarepharm Ltd proposals

2.9 The Applicant in its application indicates that it currently has core opening hours totalling 44 hours per week.

2.10 The Applicant seeks to reduce the total number of core opening hours by closing on Saturdays. The opening hours from Monday to Friday would remain the same at 8.30am to 12.30pm and 2.30pm to 6.30pm, a total of 40 core hours.

Assessment

2.11 In this case, the Applicant provided the following information in its application form dated 5 July 2023:

2.11.1 "This is an application to permanently change core opening hours.

Please insert below the current core opening hours for these premises.

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total
08.30-12.30 14.30-18.30	08.30-12.30 14.30-18.30	08.30-12.30 14.30-18.30	08.30-12.30 14.30-18.30	08.30-12.30 14.30-18.30	09.00-13.00	Nil	44

Please insert below the proposed core opening hours for these premises.

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total
08.30-12.30 14.30-18.30	08.30-12.30 14.30-18.30	08.30-12.30 14.30-18.30	08.30-12.30 14.30-18.30	08.30-12.30 14.30-18.30	Nil	Nil	40

If this is a permanent change, please state below the date from which you would like the change to take effect:

1st September 2023

...

Please provide information that demonstrates that your proposed core opening hours will:

- either maintain as necessary the existing level of service provision for people in the area of the pharmacy, or other likely users of the pharmacy premises; or
- maintain a sustainable level of adequate service provision for the people in the area of the pharmacy, in circumstances where maintaining the existing level of service provision is either unnecessary or not a realistically achievable outcome.

Paragraph 26 of Schedule 4 to the Regulations (as amended on 25th May 2023) makes provision for pharmacy contractors to apply to the ICB to change the core hours for which they are obliged to provide pharmaceutical services.

Paragraph 24 of Schedule 4 discusses the matters the ICB must consider when determining such an application. In granting such an application, it must ensure it will:

(a) maintain as necessary the existing level of service provision for the people in that area or other likely users of the pharmacy premises; or

(b) maintain a sustainable level of adequate service provision for the people in that area or other likely users of the pharmacy premises, in circumstances where maintaining the existing level of service provision is either unnecessary or not a realistically achievable outcome.

It is our position that, in accordance with these new regulations, approving our application is necessary to ensure an adequate level of service provision is maintained, and that the existing level of provision is not necessary and is also not realistically achievable.

The context of this application is the increasing pressure felt by pharmacy contractors in respect of the linked matters of funding pressures and pharmacist recruitment.

Pharmacist resourcing presents massive challenges to contractors as present, and the recruitment issues facing the profession have been widely publicised. The combination of reduced numbers of EU pharmacists and a massive recruitment drive in PCNs and GP surgeries have left the community pharmacy sector with an enormous shortfall of pharmacists. This has resulted in frequent pharmacy closures where it has been impossible to secure locum cover.

As the ICB will be aware, this is felt particularly acutely in the south-west of England and the issue is most acute at the weekends. In order to secure cover on Saturdays we have no choice but to pay exorbitant locum rates (provided we can actually find locums) and this places an unsustainable burden on our business.

As a result, maintaining pharmacy viability and meeting contractual obligations in respect of core opening hours is particularly challenging. This is exacerbated by the ongoing funding challenges faced by the profession.

Where costs outstrip income, pharmacy businesses are no longer viable and have no choice but to close. The ICB will be aware that this outcome is becoming increasingly common. It is our position that our current core hours are not sustainable and, if left unaddressed, the viability of our business is at risk.

We maintain, therefore, that granting this application is necessary to “maintain a sustainable level of adequate service provision for the people in the area” as this will reduce the risk of our pharmacy closing. The loss of our pharmacy may mean there is no longer adequate provision to meet patient needs in Honiton.

In order to grant the application, the ICB must be satisfied that existing provision is “unnecessary or not realistically achievable”.

It is our position that existing provision, specifically on Saturday mornings is not necessary for the following reasons:

1 Alternative provision

There is a Boots pharmacy located at:

123-125 HIGH STREET
HONITON
DEVON
EX14 1HR

This pharmacy is open from 9am to 5pm on Saturdays, and is located only 400m away from our pharmacy on foot, a walk of approximately 5 minutes.

There is also a Tesco pharmacy located at:

BATTISHORNE WAY
SIDMOUTH ROAD
HONITON
DEVON
EX14 2XD

This pharmacy is open from 9am to 6pm on Saturdays, and is located only 1.5 miles away from our pharmacy by road, a drive time of less than 5 minutes.

Honiton is a relatively affluent town with a largely rural area, so car ownership is high. Residents currently use the Tesco store for their 'weekly shop' so find it easy to access. For those residents who do not have access to a car, if they are accustomed to accessing our pharmacy on a Saturday, they can easily access Boots a short walk away.

Any patient requiring pharmaceutical services on a Saturday will be able to access the Tesco or Boots pharmacies over a 9-hour period. It is our position that this level of service is more than adequate in the town the size of Honiton.

The Saturday hours provided by our pharmacy are therefore unnecessary on the grounds there is more than adequate alternative provision by other contractors.

Demand

The Saturday service provided by our pharmacy is also unnecessary on the grounds of demand. This is evidenced by patient numbers attending the pharmacy on a Saturday, which shows demand is minimal.

Given the limited demand at present for pharmaceutical services at our pharmacy, it is clear that this service is unnecessary.

Not realistically achievable

As discussed above, securing pharmacist cover for Saturday mornings in Honiton is particularly challenging for the reasons provided.

Sustaining these opening hours in the long-terms is not realistically achievable.

44 core hours

Finally, whilst not directly relevant to this application, we note that according to the ICB records, this pharmacy (which we recently acquired from Lloyds Pharmacy before relocating to the current premises) has 44 core hours at present.

The Primary Care Appeals committee at NHS Resolution has previously found that contractor can only be required to open for more than 40 core hours where a direction to do so has been issued by the commissioner. We have checked with the previous owners, Lloyds Pharmacy Limited, and they are not aware that any such direction to open for 44 core hours was ever issued to this pharmacy.

We therefore believe this provides further grounds for our case to cease provision of our current Saturday opening hours.

In conclusion, we urge the ICB to approve this application to ensure the sustainable provision of adequate pharmaceutical services in Honiton for the long-term.”

2.12 In a letter to the Applicant dated 24 August 2023 the Commissioner stated:

2.12.1 “I refer to the application to change the contractual opening hours for the above pharmacy. The NHS South West Pharmaceutical Services Regulations Committee (PSRC) considered your request on the 3rd of August 2023, please see details of the decision below.

- The SW Committee noted the proposal to remove the four Saturday opening hours and the applicants’ comments round the additional four hours above the required 40 Core Hours, noting there is no direction in place for the additional four core hours.
- The SW Committee noted there was no response from any interested parties consulted, so had no other local considerations to factor into its decision making.
- It was noted the pharmacy was previously owned by Lloyds Pharmacy and Clarepharm took over in October 2022, then the pharmacy related [sic] in June 2023. It was noted the current owner took on the pharmacy with the knowledge that the pharmacy has 44 Core hours, of which four are on Saturdays.
- The change to the Regulations in May 2023 was noted in terms of the requirement to demonstrate that Core hours are set so as to sustain the necessary level of adequate service provision, but the SW Committee has no evidence of when patient demand is highest.
- The SW Committee noted there is reasonable alternative access available at weekends from the other pharmacies in Honiton, however, Honiton is a market town with a population of around 12,000 and secure provision for patients needs to be within Honiton given its geographical location.

- It was noted the applicant comment that the hours currently offered do not match the patient demand would be better supported if we had details of activity on Saturdays. It was noted no patient survey appears to have been undertaken by the applicant so there is no evidence of the patient perspective.
- The SW Committee noted that maintaining easy access to services evenings and weekends is important, not just for prescriptions but for the wider range of services and advice pharmacies provide to patients. It is particularly important this is maintained at weekends to ease pressure on urgent care services.
- The SW Committee agreed the applicant could consider a move to 40 Core hours by looking at the spread of hours throughout the week at a time that will be more suitable to patient need.
- The application is **REFUSED**.
- The application was therefore **declined**, and the contractual opening hours of the pharmacy remain as follows:

CORE		SUPPLEMENTARY	
Monday	08.30-12.30 & 14.30-18.30	Monday	12.30-14.30
Tuesday	08.30-12.30 & 14.30-18.30	Tuesday	12.30-14.30
Wednesday	08.30-12.30 & 14.30-18.30	Wednesday	12.30-14.30
Thursday	08.30-12.30 & 14.30-18.30	Thursday	12.30-14.30
Friday	08.30-12.30 & 14.30-18.30	Friday	12.30-14.30
Saturday	09:00-13.00	Saturday	-
Sunday	Closed	Sunday	Closed

Please note that any variation to contractual opening hours, without prior consent, will be deemed a breach of terms of service. Performance related sanctions, as directed within the 2013 Regulations, may be imposed where a breach occurs.

You have a right of appeal against the decision not to allow the amendment to Core Hours. Any appeal must contain a concise statement of the facts and contentions on which you intend to rely and should be submitted in writing within 30 days to: nhsr.appeals@nhs.net or by post to:

NHS Resolution
8th Floor 10 South Colonnade
Canary Wharf London
E14 4PU

If you wish to change the hours in the future, you will still need to complete and submit a further notification form to NHS England.”

2.13 In a letter to NHS Resolution dated 30 August 2023, Pharmacy Sales and Consultancy, on behalf of the Applicant, stated:

2.13.1 “Our client has been notified by the NHS South West Collaborative Commissioning Hub that the above application has been refused. I have enclosed a copy of their decision letter for your information.

Our client wishes to appeal this decision. The key ground for this appeal is that the NHS South West Pharmaceutical Services Regulations Committee (PSRC) failed to properly consider The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 when making its decision. Instead it considered matters outside those regulations when it refused the application.

We have enclosed a copy of our client’s original application and will not repeat those comments verbatim. Instead we have responded to each of the comments made in the PSRC’s decision letter below.

The SW Committee noted the proposal to remove the four Saturday opening hours and the applicants’ comments round [sic] the additional four hours above the required 40 Core Hours, noting there is no direction in place for the additional four core hours.

In the absence of any direction relating to the 4 hours that exceed the contractual 40 hours, our client maintains its position that it may reduce its core hours to 40. In our client’s opinion, the ICB has failed to adequately explain why this cannot be achieved by removing the four core hours on a Saturday.

The SW Committee noted there was no response from any interested parties consulted, so had no other local considerations to factor into its decision making.

The lack of any objections supports our client’s view that there will be no adverse effect on the provision of pharmaceutical services as a result of the change to core hours it proposes.

It was noted the pharmacy was previously owned by Lloyds Pharmacy and Clarepharm took over in October 2022, then the pharmacy related in June 2023. It was noted the current owner took on the pharmacy with the knowledge that the pharmacy has 44 Core hours, of which four are on Saturdays.

It is not disputed that the current owner took on the pharmacy in the knowledge there was discrepancy with the core hours. However that is not relevant to the committee’s decision in this case. As the current owner of the pharmacy, our client is entitled to submit an application for a change of core hours regardless of how long it has owned the pharmacy.

The change to the Regulations in May 2023 was noted in terms of the requirement to demonstrate that Core hours are set so as to sustain the necessary level of adequate service provision, but the SW Committee has no evidence of when patient demand is highest.

The regulations require the decision maker to consider whether 'maintaining the existing level of service provision isunnecessary'. Typically the current level of service provision might be deemed to be unnecessary because either:

- i. There is no demand for that service or;
- ii. The service is available from one or more alternative providers and the current level of provision exceeds that which is necessary to ensure patients have reasonable access to pharmaceutical services.

The SW Committee has commented that there is no evidence of when patient demand is highest. This does not form part of the legal test. Despite the fact that patient demand on Saturday mornings is significantly lower than during the weekdays (as a result of the nearby medical centre being closed), our client is not required to provide evidence of this. Instead clear evidence has been provided that there are two alternative providers of pharmaceutical services available on Saturday mornings, each of which is readily accessible to patients.

If, following the proposed closure of our client's premises on Saturday mornings, patients still have good access to pharmaceutical services in Honiton, then it is clear that the previous level of service provision was unnecessary.

The SW Committee noted there is reasonable alternative access available at weekends from the other pharmacies in Honiton, however, Honiton is a market town with a population of around 12,000 and secure provision for patients needs to be within Honiton given its geographical location.

The committee appears to contradict itself with this comment. It acknowledges that there is reasonable alternative access in the town but then goes on to comment on the need for secure provision to be available for residents. If there is reasonable alternative access then clearly there will still be secure provision if this application is granted.

It was noted the applicant comment that the hours currently offered do not match the patient demand would be better supported if we had details of activity on Saturdays. It was noted no patient survey appears to have been undertaken by the applicant so there is no evidence of the patient perspective.

Whilst our client is able to undertake a survey of Saturday activity, for the reasons we have already provided the regulations do not require it to do so. In any event, the SW Committee elected to refuse the application rather than to go back to our client seeking additional information, so providing the SW Committee with a survey at this stage serves no purpose given that the decision has already been made.

The SW Committee noted that maintaining easy access to services evenings and weekends is important, not just for prescriptions but for the wider range of services and advice pharmacies provide to patients. It is particularly important this is maintained at weekends to ease pressure on urgent care services.

We do not dispute this comment but have already provided evidence in respect of the alternative provision that is available and the SW Committee acknowledged that this is the case. It is not clear, therefore, why the committee refused our client's application.

The SW Committee agreed the applicant could consider a move to 40 Core hours by looking at the spread of hours throughout the week at a time that will be more suitable to patient need.

Our client maintains its position that patient need is greatest from Monday to Friday and that it already has core hours that meets these needs. In summary, the SW Committee has erred in its decision by failing to consider the relevant legal tests within the regulations. That being the case we urge Primary Care Appeals to overturn the decision of ICB and grant this application accordingly.

Our clients would wish to attend an oral hearing should the committee decide to convene one."

2.14 In a letter to NHS Resolution dated 28 September 2023 the Commissioner stated:

2.14.1 "The Southwest PSRC agrees that there are more than 40 core hours listed and there is no direction in place. It has not been possible to establish for certain whether this is an error in capturing the core hours at some point or if a direction should have been issued in the past but was not. The Southwest PSRC is happy to work with the appellant to get core hours to 40 but this needs to be in such a way that protects patient access to pharmaceutical services through the week and at weekends. The appellant acquired the pharmacy from another company relatively recently and so would have been aware of the nature of the opening hours.

The South West PSRC was aware of the alteration in the Regulations around hours and would respectfully suggest that agreeing the appellant's application would fail the first test (*proposed core opening hours are such as to maintain as necessary the existing level of service for people in the area of the pharmacy premises or other likely users of them*) as that would clearly result in a reduction in the level of service for people in the area.

That leaves the Southwest PSRC having to make an assessment regarding the maintenance of a sustainable level of adequate service provision for the people in the area of the pharmacy premises or other likely users of them, in circumstances where maintaining the existing level of service provision is either unnecessary or not a realistically achievable outcome. It is true there is no obligation on the appellant to provide activity data but without it, and comparative data from the past it is difficult to assess what adequate service provision looks like.

In the original application the appellant asserts that it is not necessary for the pharmacy to be open on Saturdays because there are other pharmacies in Honiton. They also assert that there are funding pressures, difficulties getting locums and low activity. They also assert that the 2 other pharmacies provide sufficient access on Saturdays. The

Southwest PSRC would respectfully suggest that these are assertions with no data or evidence to back them up. Clearly at some point the relevant contractor was of the view that there was a need for this pharmacy on a Saturday morning and so included Saturday opening hours.

Honiton has just the 3 pharmacies, if this application is granted approval to amend core hours on a Saturday and one [sic] anything happens to one of the other 2 then instead of 3 pharmacies on a Saturday there is suddenly only 1. The next nearest pharmacy open on a Saturday would be in Ottery St Mary about 6 miles away.

The Southwest PSRC would respectfully request that its decision be upheld while acknowledging the need to agree with the appellant when the 40 core hours should be.”

2.15 In a letter to NHS Resolution dated 11 October 2023 Pharmacy Sales and Consultancy, on behalf of the Applicant, stated:

2.15.1 “We note that the only comments that have been submitted are those from [NH] at the South West Collaborative Commissioning Hub. We respond to those comments in the order raised.

We note that the Southwest PSRC acknowledges that the pharmacy is currently trading for more than 40 core hours and that there is no direction in place in relation to those hours over and above the 40 hours required by the Regulations. In the absence of any such direction, it is clear that NHS England (or the relevant commissioner that was in place at the time any such hours were committed to their record), have not previously determined that there was any need for this pharmacy to open for more than 40 core hours.

It is reasonable to assume, therefore, that no exercise was carried out at that time which concluded there were certain times of the day, or days of the week, where it was determined that pharmaceutical services must be provided to secure adequate provision. It is not necessarily the case, therefore, that the core hours committed to originally are reflective of any specific need during those hours.

We note that the PSRC [sic] persist in referring to the fact our client acquired this pharmacy recently and was therefore “aware of the nature of the opening hours”.

With respect to the PRSC, that has no relevance to the regulatory tests is it required to consider. My client, as the current contractor, has a right to make an application to change its core hours regardless of whether or not is has recently acquired the pharmacy.

The PSRC go on to make the following comments:

“The South West PSRC was aware of the alteration in the Regulations around hours and would respectfully suggest that agreeing the appellant’s application would fail the first test (proposed core opening hours are such as to maintain as necessary the existing level of service for people in the area of the pharmacy premises or other likely users of

them) as that would clearly result in a reduction in the level of service for people in the area.”

We have no material comments to make on this paragraph save to say that the wording used in the Regulations is to “maintain **as necessary** the existing level of service provision”. [Applicant’s emphasis]

The addition of the words “as necessary” leaves room for the decision maker to decide whether the current levels of provision are necessary. Where they are not, there is room for it to consider whether any reduction in the level of service (in this case due to the reduction in hours) amounts to a material reduction in the level of service. For the reasons our client has provided previously, we believe there will not be a material reduction.

The PSRC then goes on to consider the second, related test, i.e. whether maintaining the existing level of service provision is either *unnecessary or not a realistically achievable outcome*. [Applicant’s emphasis]

Our client has commented on this test previously but we add further comments here in response to the new points raised by the PSRC.

We disagree with the suggestion that activity data or comparative data is necessary to “assess what adequate service provision looks like”. With respect to the PSRC we would suggest this is largely a matter of common sense.

Firstly the Honiton medical centre does not open at the weekends at all. As the nearest pharmacy to this medical centre, in an area which otherwise has very little supporting trade, it is clear that demand for pharmaceutical services at this location are largely driven by whether or not the surgery is open.

Furthermore, and we would suggest of even greater relevance, it is a matter of fact that there is excellent alternative provision pharmaceutical services in the town on Saturday mornings. This is provided by both Boots, which is located only 400 metres away in the heart of the High Street, and Tesco which is the main supermarket serving the town. Both of these pharmacies open for the hours our client is proposing to close and both are located precisely where local residents do their shopping on a Saturday, so are highly accessible.

With respect to the PSRC’s comments, we would suggest that the evidence that these alternative pharmacies exist is plain to see. It is not correct to suggest that there is “no data or evidence to back up” our client’s comments. The PSRC is very aware that these two pharmacies open on Saturday mornings and it will also be aware that there is no evidence of them closing regularly or failing to provide pharmaceutical services on Saturdays.

The final comment made by the PSRC is particularly difficult to accept. It appears that one of their key reasons for refusing our client’s application is because there are “only three pharmacies in the town”. It states that “if anything happens to one of the other 2 then instead of 3

pharmacies on a Saturday there is suddenly only 1". Putting aside the fact that it is not clear why anything should happen to one of the other two pharmacies, even if that eventuality occurred, by their own admission there will still be a pharmacy open in Honiton on a Saturday morning. That being the case patients will still have access to pharmaceutical services. The logic applied by the PSRC is therefore difficult to follow."

2.16 I note the following:

2.16.1 the Applicant's core opening hours total 44 hours and the Applicant seeks to change the days on which or times at which the Applicant is obliged to provide pharmaceutical services at its pharmacy premises in a way that reduces the total number of hours for which the Applicant is obliged to provide pharmaceutical services.

2.16.2 The Applicant seeks to reduce the total number of core opening hours by closing on Saturdays. The opening hours from Monday to Friday would remain the same at 8.30am to 12.30pm and 2.30pm to 6.30pm, a total of 40 core hours.

2.17 There is no suggestion by either party that a current direction has been issued to the Applicant regarding their opening hours pursuant to Regulation 65(4) and (5) of the Regulations. In fact both parties state that there is no direction in place. I note the Commissioner's comment that *"It has not been possible to establish for certain whether this is an error in capturing the core hours at some point or if a direction should have been issued in the past but was not."*

2.18 The Regulations, which came into force on 1 April 2013, have been amended a number of times. Certain amendments, relating to pharmacy premises opening hours, came into force with effect from 25 May 2023.

2.19 The application to change the hours was made by the Applicant on 5 July 2023 and a decision was made by the Commissioner on 24 August 2023. The decision was appealed to NHS Resolution by letter dated 30 August 2023. I am of the view that the application and subsequent appeal should be considered against the Regulations as amended with effect from 25 May 2023.

2.20 The Applicant has sought to change the days and times at which it is obliged to provide pharmaceutical services under paragraph 26 of Schedule 4, Part 3, "Hours of opening".

2.21 Paragraph 26(1) states:

"26.— (1) An NHS pharmacist (P) may apply to the NHSCB for it to change the days on which or times at which P is obliged to provide pharmaceutical services during core opening hours at P's pharmacy premises in a way that—

(a) reduces the total number of hours for which P is obliged to provide pharmaceutical services at those premises each week ...; or

(b) keeps that total number of hours the same."

2.22 I have first considered paragraph 26(2) of Schedule 4 of the Regulations, which reads as follows:

"Except where sub-paragraph (2A) applies, where P makes an application under sub-paragraph (1), as part of that application P must provide the NHSCB with such information as the NHSCB may reasonably request in respect of the matters that NHS England must seek to ensure pursuant to paragraph 24(1).

2.23 I note that paragraph 26(2A) does not apply in this instance as a 100 hour condition does not apply, therefore I am of the view that paragraph 24(1) does apply to this application and it is on this basis that the Applicant applied to the Commissioner to amend its core opening hours. I have therefore proceeded to consider the application before me in accordance with paragraph 24(1).

2.24 Paragraph 24(1) reads as follows:

"24 (1) Subject to paragraph 26(2A), where NHS England issues a direction for setting any days or times for opening hours under this Part, or determines them without issuing a direction, it must in doing so seek to ensure that the days and times as which pharmacy premises are open for the provision of pharmaceutical services in the area in which the premises that are the subject of the direction are located are such as –

(a) to maintain as necessary the existing level of service provision for the people in that area or other likely users of the pharmacy premises; or

(b) to maintain a sustainable level of adequate service provision for the people in that area or other likely users of the pharmacy premises, in circumstances where maintaining the existing level of service provision is either unnecessary or not a realistically achievable outcome.

2.25 Paragraph 24(2) states:

(2) In considering the matters mentioned in sub-paragraph (1), the NHSCB –

(a) must treat any local pharmaceutical services being provided in its area as if they were pharmaceutical services being so provided, and

(b) may have regard to any pharmaceutical services that are being provided in its area during supplementary opening hours.

2.26 I will start by considering the application of paragraph 24(1)(a) and whether the proposed hours are such as to maintain as necessary the existing level of service provision for the people in that area or other likely users of the pharmacy premises. I will then consider the application of paragraph 24(1)(b) if that is required.

2.27 To properly assess the application against paragraph 24(1)(a), I need to determine the existing level of service provision. I then need to consider whether it is necessary to maintain the existing level of service provision. If it is necessary to maintain the existing level of service provision, I need to consider whether, despite the proposed change of hours, the existing level of service provision to people in the area or other likely users would be maintained, e.g. by nearby pharmacies being open and providing the same level of service provision.

2.28 If I consider it unnecessary to maintain the existing level of service provision or that it is necessary to maintain the existing level of service provision but doing

so is not a realistically achievable outcome, then I need to consider paragraph 24(1)(b) and determine whether the proposed change of hours are such that a sustainable level of adequate service provision would be maintained.

- 2.29 I therefore need to be provided with sufficient information to understand a range of matters, starting with the existing level of service provision. The references to days and times in paragraph 24(1) leads me to consider that the reference to "level" of service provision in paragraph 24(1)(a) is mainly focused on the days and times services are provided. I would point out that "level" of service provision could also refer to other characteristics of the service, such as types and range of services provided, geographical access to services provided, other aspects of physical access aside from location, and the quality of services provided.
- 2.30 The existing level of service provision has been outlined by the Applicant, in its own core hours provision, and by an indication of the hours that pharmacies in the local area are open on Saturdays, being the day on which the Applicant wishes to close.
- 2.31 I have next considered whether it is necessary to maintain the existing level of service provision. As the Applicant is looking to reduce the number of hours each week that services are provided, then from a pure "number of hours of service provision each week" perspective, the existing level of service provision would not be maintained such that consideration of whether it is necessary to maintain the level of service provision is needed.
- 2.32 The level of service provision at the Applicant's premises on a Saturday is not being maintained. I consider it appropriate to determine if it is necessary to maintain the existing level of service provision and then, if deemed necessary, consider if the opening hours of other pharmacies mean that level is maintained.
- 2.33 To determine whether it is necessary to maintain the existing level of service provision, I have noted the comments by the Applicant regarding those using the pharmacy. If I am satisfied that there is reliable evidence indicating no users of the pharmacy on/at the relevant days/times that the pharmacy wishes to close, this might support an argument that maintaining the existing level of service provision is not necessary.
- 2.34 I note the Applicant states in its application that demand is minimal on a Saturday and that this is evidenced by patient numbers, however no supporting information has been provided as to what constitutes 'minimal'.
- 2.35 I note the Applicant's comment that "*We disagree with the suggestion that activity data or comparative data is necessary to "assess what adequate service provision looks like"*". The Applicant goes on to comment that Honiton Medical Centre does not open on weekends and that as the area has little supporting trade, demand for pharmaceutical services at the pharmacy is largely dependent on whether or not the surgery is open.
- 2.36 I am mindful that as well as dispensing prescriptions, a pharmacy provides other essential services in accordance with its terms of service such as advice. I therefore consider that it is relevant to have information as to why persons are using the pharmacy at the times in question. It is difficult to draw conclusions about the necessity of maintaining the existing level of service provision if there

is no information on what specific services, if any, are being provided at those times.

- 2.37 Without this information it is difficult to make an assessment of whether it is necessary to maintain the existing level of service provision and this in turn makes it difficult to apply paragraph 24(1)(a). I consider it reasonable to take the position that unless I am provided with evidence to the contrary, I should consider that it is necessary to maintain the existing level of service provision.
- 2.38 Having determined that it is reasonable to assume that maintaining the existing level of service provision is necessary, I now need to consider if, despite the changes to hours, there is maintenance of the existing level of service provision. The Applicant cannot maintain this as it is changing its hours but I note the undisputed information from the Applicant with regard to other pharmacies in the area that, between them, have opening hours during the times that the Applicant is proposing to close, namely Boots and Tesco.
- 2.39 If I consider that the characteristics of other pharmacies, e.g. where they are located, their access, the services provided and the times they are open, means that the level of service provision is maintained for people in the local area or other likely users of the pharmacy, then I am able to grant the application under paragraph 24(1)(a).
- 2.40 The Applicant has provided some information regarding access to those pharmacies for those who currently access its own pharmacy and how they might travel to find alternative pharmaceutical services. The Applicant has considered a mix of people who drive to the Applicant's pharmacy and those who walk.
- 2.41 It is worth noting that characteristics of the persons using the pharmacy might be relevant here as well as from where they start their journey to the pharmacy. I do not consider that every single individual need should be considered at length in this regard but it would be helpful to have this information to be certain that the existing level of service provision would be maintained via local pharmacies.
- 2.42 According to the Applicant, Boots Pharmacy is open from 9am to 5pm on Saturdays and is located 400 metres away from the Applicant's pharmacy which they comment takes approximately 5 minutes to walk. I have not been provided with any details of the route involved, which I assume starts at the Applicant's pharmacy. I am therefore unable to determine whether the route on foot is suitable for all those needing to undertake the journey in order to access pharmaceutical services, for example whether there is sufficient street lighting, dropped kerbs and pedestrian crossings where necessary.
- 2.43 The Applicant has also provided details of access to Tesco pharmacy which is open from 9am to 6pm on Saturdays at a distance of 1.5 miles from the Applicant's pharmacy. The Applicant states that this is a drive of less than 5 minutes and that Honiton is a relatively affluent town with high car ownership.
- 2.44 Whilst the existing level of service provision may be maintained for those with access to a car, due to a lack of more detailed information I am unable to conclude the same for those who need to access a pharmacy on foot or by public transport.

- 2.45 I am therefore struggling to be satisfied that the existing level of service provision would be maintained by virtue of the existence of other local pharmacies.
- 2.46 I have decided that it is necessary to maintain the current service provision but, due to the cumulative effect of:
- 2.46.1 a lack of information about the demand for services at the pharmacy on Saturdays;
- 2.46.2 a lack of information about the services being provided during the hours the Applicant is proposing to close; and
- 2.46.3 a lack of information regarding the journey to alternative pharmacies for those without access to private transport,
- 2.47 I am not satisfied that there will be maintenance of the existing level of service provision by virtue of other pharmacies in the area open on Saturdays.
- 2.48 I therefore next consider if I need to have regard to paragraph 24(1)(b) which states that I must seek to ensure that the changed hours are such as to:
- “maintain a sustainable level of adequate service provision for the people in that area or other likely users of the pharmacy premises, in circumstances where maintaining the existing level of service provision is either unnecessary or not a realistically achievable outcome”.*
- 2.49 I have already determined that it is necessary to maintain the existing level of service provision so reference in paragraph 24(1)(b) to *“in circumstances where maintaining the existing level of service provision is ... unnecessary”* is not relevant.
- 2.50 The Applicant has stated that *“The context of this application is the increasing pressure felt by pharmacy contractors in respect of the linked matters of funding pressures and pharmacist recruitment”* and that *“In order to secure cover on Saturdays we have no choice but to pay exorbitant locum rates (provided we can actually find locums) and this places an unsustainable burden on our business.”* I note that the Applicant seeks to rely on the second part of paragraph 24(1)(b), that maintaining the existing level of service provision is not a realistically achievable outcome. I consider that I need to determine if it is or is not a realistically achievable outcome and if I determine that it is, then I need to consider if the amended hours are such as to maintain a sustainable level of service provision.
- 2.51 On the point of whether maintaining the existing level of service provision is not a realistically achievable outcome, I consider that no evidence has been put forward to support the Applicant's statement that it is necessary to pay “exorbitant rates” in order to secure locums. No evidence of costs for locums at different times has been provided. No evidence of what efforts have been undertaken to source locums has been provided. There is no explanation as to why locums rather than employees have to be used. I also note that whilst there is reference to *“frequent pharmacy closures”* no further detail has been supplied for consideration. The Applicant appears to be saying it is not sustainable to keep paying locums to cover these hours but it has not presented evidence that

suggests these fees are compromising the economic viability of its operations at the weekend or otherwise.

- 2.52 The wording of paragraph 24(1)(b) is such that maintaining existing service levels must not be realistically achievable before considering a sustainable level of adequate provision. I consider that this sets a fairly high bar as to the level of difficulty that the Applicant must find themselves in. I do not consider that sufficient evidence has been provided to indicate that the economic and practical viability of the current opening hours has been compromised. The use of the words “*particularly challenging*” by the Applicant suggests that it has been achievable, but difficult. I therefore consider that maintaining the existing level of service is a realistically achievable outcome and therefore the Applicant cannot rely on paragraph 24(1)(b).
- 2.53 I am mindful that the provision of pharmaceutical services is greater than the dispensing of prescriptions and that maintaining a level of service provision includes all services that the pharmacy may offer, including additional enhanced and advanced services that may be commissioned. I am of the view that I have not been provided with sufficient information to demonstrate how the proposed change of hours would maintain, as necessary, the existing levels of service provision.
- 2.54 I am therefore minded not to agree the change of the Applicant’s core opening hours.
- 2.55 In determining an application made under paragraph 26(1) of Schedule 4 of the Regulations, paragraph 26(4) indicates that the Commissioner must:
- 2.55.1 issue a direction (which replaces any existing direction) which meets the requirements of sub-paragraphs (4A), (5) and (6) and which has the effect of either granting the application in whole or in part;
- 2.55.2 confirm any existing direction in respect of the times at which the pharmacist must provide pharmaceutical services at the pharmacy premises; or
- 2.55.3 either:
- 2.55.3.1 revoke, without replacing it, any existing direction in respect of the times at which the pharmacist must provide pharmaceutical services at the pharmacy premises where this has the effect of granting the application in whole or in part; or
- 2.55.3.2 in a case where there is no existing direction, issue no direction,
- 2.56 Prior to 1 April 2023, NHS England was responsible for the commissioning of pharmaceutical services. Integrated Care Boards have since taken on delegated responsibility for the commissioning of pharmaceutical services. Therefore it would have been NHS England who was responsible for issuing a direction to the previous owner in relation to the hours above 40 core hours.
- 2.57 I note from the Commissioner’s representations on the appeal that it “*agrees that there are more than 40 core hours listed and there is no direction in place*”. The parties are in agreement that there is no direction in place. I note the Commissioner’s comment that the Applicant “*acquired the pharmacy from*

another company relatively recently and so would have been aware of the nature of the opening hours."

- 2.58 The rationale behind the Commissioner's decision to refuse the Applicant's application was that it would fail the first test i.e. that the proposed core opening hours are such as to maintain as necessary the existing level of service for people in the area of the pharmacy premises or other likely users of them as agreeing the application would result in a reduction of the level of service for people in the area. The Commissioner also considered that the Applicant had failed to provide any data or evidence to support its assertions regarding the maintenance of a sustainable level of adequate service provision for the people in the area of the pharmacy premises or other likely users of them, in circumstances where maintaining the existing level of service provision is either unnecessary or not a realistically achievable outcome.
- 2.59 In this instance, parties are in agreement that there is no direction in place to provide more than 40 hours per week and I have not been provided with any evidence to suggest otherwise. I am therefore satisfied that NHS England has not issued a direction in relation to the Applicant's core opening hours.
- 2.60 Applications to change core hours are determined in accordance with paragraph 26(4) of Schedule 4 of the Regulations. This causes me some difficulty as the Commissioner was required to determine the application in accordance with paragraph 26(4) under which there is no express option to simply refuse the application due to services being provided for more than 40 core hours despite there being no existing direction. Paragraph 26(4)(c)(ii) expressly states that I must, in a case where there is no direction, issue no direction.
- 2.61 I also note that the Regulations do not envisage this situation arising (i.e. a pharmacy providing more than 40 hours a week without a direction in place) and therefore there is no guidance in the Regulations to determine which of the days and times during which services are to be provided going forward constitute core opening hours, or put a different way, of the 40 hours that the Applicant is required to provide services, which are to be considered the core days and times. This leads to an unsatisfactory situation in which neither party is clear as to the days on which and times at which the 40 core opening hours are to be provided.
- 2.62 However, I consider that the amendments made to the Regulations provide the ability for me to make such a determination. Paragraph 24(1) now contains new wording in relation to days or times for opening hours - "[...]or *determines them without issuing a direction*". I have provided the complete extract at paragraph 2.24 above.
- 2.63 The inclusion of this wording indicates to me that the Commissioner does have a power to determine the days and times at which the 40 core opening hours are provided and this is without the need to issue a direction. This would not contradict paragraph 26(4)(c)(ii) as, there is no existing direction in place and there is no direction being issued. I therefore consider that this new wording allows the determination by the Commissioner of the days and times that the 40 core opening hours are provided.
- 2.64 I note that the rest of paragraph 24(1) and the legal test that needs to be considered alludes to a direction. However, given the novel nature of the

situation where a pharmacy is clearly operating outside of 40 hours without a direction, and where each of these hours appears to be core hours, it would make sense that the Commissioner is able to determine the 40 core opening hours without a direction.

- 2.65 I therefore determine that the Commissioner was able to determine the Applicant's core hours, without issuing a direction as per paragraph 24(1) and by applying the legal test set out in paragraph 24(1). I note that the Commissioner applied the legal tests in paragraph 24(1) but refused the application indicating that the reduction to 40 core opening hours should focus on reducing hours during the week rather than Saturday.
- 2.66 I have indicated that I am minded not to agree the change of the Applicant's core opening hours on the basis of a lack of information on various points. That would usually mean I would confirm the decision of the Commissioner albeit for slightly different reasons. But that would leave me in the unwelcome position of making a determination that the Applicant must continue to provide services for more than 40 hours a week without a direction.
- 2.67 That is not satisfactory but, in this novel situation unforeseen by the Regulations, I consider that I have little choice. I cannot determine the 40 core opening hours on the basis of the information provided despite being enabled by the new wording in paragraph 24(1) to do so. I would urge the Applicant to gather information as to the use of the pharmacy at different days and times and apply again to change its core hours which should then enable the Commissioner to make an assessment of the most appropriate 40 core opening hours. The Commissioner can then make a determination by applying the legal tests in paragraph 24(1). Provided the level of information is adequate, the Commissioner can make that determination.
- 2.68 I consider I am unable to grant the application on the basis of lack of information as indicated earlier in this determination. The only option left to me is therefore to confirm the action taken by the Commissioner in refusing the Applicant's application but substituting the reasons with the reasons I set out earlier in this determination.

3. Determination

- 3.1 I consider that, on the basis of the information provided to me, it is necessary to maintain the existing level of service provision and that not enough information has been provided for me to consider that maintaining the existing level of service provision is not a realistically achievable outcome. Although this leaves an undesirable situation, where the Applicant continues to provide 44 core opening hours without a direction being in place, I consider the lack of information does not enable me acting reasonably to make a determination of the days and times of the 40 core opening hours.
- 3.2 I consider that the only option open to me is therefore to confirm the action taken by the Commissioner to refuse the application.