

28 May 2025

FILE REF:

SHA/26525

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10 South Colonnade
Canary Wharf
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Tel: 020 3928 2000
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COMMISSIONER:

**HERTFORDSHIRE AND WEST
ESSEX ICB
("the Commissioner")**

PHARMACIST:

**MEDINO ONLINE LTD
("the Applicant")**

PREMISES:

**MEDINO ONLINE LTD (FQF90)
UNIT 6, UNION PARK
GROVEBURY ROAD
LEIGHTON BUZZARD
BEDFORDSHIRE, LU7 4UX**

**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 Based on the information provided, I am not satisfied that the pharmaceutical services provision that would result from the Applicant's proposed hours would maintain as necessary the existing level of service provision for the people in that area or other likely users of the pharmacy premises.
- 1.2 Therefore I confirm the decision of the Commissioner to reject the change of hours application.

A copy of this decision is being sent to:

Medino Online Ltd
Hertfordshire and West Essex ICB

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10 South Colonnade
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E14 4PU

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**THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL AND LOCAL PHARMACEUTICAL
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**SCHEDULE 4 [Terms of Service of NHS Pharmacists]
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 keep the total number of core opening hours the same while offering a different distribution of these hours during the week.
- 1.2 The Commissioner has refused the application. The Applicant seeks to appeal to NHS Resolution.

Rights of appeal

- 1.3 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").
- 1.4 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

- 1.5 A pharmacy's opening hours may be categorised as:
- 1.5.1 "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

- 1.5.2 “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

- 1.6 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:
 - 1.6.1 the proposed core opening hours in respect of the premises; and
 - 1.6.2 the total proposed opening hours for the premises (having regard to both the proposed core opening hours and any supplementary opening hours).
- 1.7 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.
- 1.8 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

- 1.9 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.
- 1.10 There is no specific right of appeal to NHS Resolution in respect of notices given under paragraph 23(6)(a).

The Applicant's proposals

- 1.11 The Applicant in its application indicates that it currently has core opening hours totalling 40 hours per week.
- 1.12 The Applicant wishes to open between 13:30 and 21:30 Monday to Friday, rather than between 9:00 and 17:00.
- 1.13 The Applicant is closed on Saturday and Sunday.

2. Application

In this case, the Applicant provided the following information in its application form and supporting information dated 18 September 2024:

- 2.1 “This is an application to permanently change core opening hours.
- 2.2 Current opening hours for these premises:

Monday	9-17
Tuesday	9-17
Wednesday	9-17
Thursday	9-17
Friday	9-17
Saturday	CLOSED
Sunday	CLOSED

2.3 Proposed core opening hours for these premises:

Monday	13.30-21.30
Tuesday	13.30-21.30
Wednesday	13.30-21.30
Thursday	13.30-21.30
Friday	13.30-21.30
Saturday	CLOSED
Sunday	CLOSED

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

2.4.1 12/12/2024

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

2.5.1 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

2.5.2 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.

2.6 As Medino is an online pharmacy, the change in core hours will not affect our existing level of service nationwide. In fact, this change is likely to improve service due to an additional Royal Mail collection at 21:00, complementing the existing 17:00 collection."

3. The Decision

In a letter to the Applicant dated 31 January 2025 the Commissioner decided to refuse the application. The Commissioner stated:

3.1 "The Pharmaceutical Services Regulations Committee (hereafter referred to as "the Committee") considers all pharmaceutical services applications on behalf of NHS Hertfordshire & West Essex ICB on behalf of all six ICBs in the East of England region, in accordance with the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended (hereafter referred to as "the Regulations").

3.2 The Committee considered this application under Schedule 4, Part 3, Paragraph 24 and 26 of The Regulations 2013.

- 3.3 This application was considered under 26(1)(b).
- 3.4 **Application to change core opening hours:** (FQF90) Medino Online Ltd, Unit 6, Union Park, Grovebury Road, Leighton Buzzard, Bedfordshire LU7 4UX.
- 3.5 The Committee considered this application under paragraph 24 and 26, Part 3, Schedule 4, of the Regulations.
- 3.6 The Committee first considered Regulation 65 – Core opening hours conditions.
- 3.7 **Is there a direction in place in respect of the pharmacy premises?**
- 3.8 The Committee noted that no direction under Regulation 65 is in existence.
- 3.9 The Committee moved on to consider paragraph 26(1), of Schedule 4 – Determination of pharmacy premises core opening hours instigated by the NHS pharmacist.
- 3.10 **Is the applicant seeking to keep the total number of core opening hours of the pharmacy premises the same, but to change when they are?**
- 3.11 The Committee agreed that the applicant is seeking to keep the total number of core opening hours the same, which is 40 core hours. The applicant is proposing to change when they are provided.
- 3.12 The Committee next considered Paragraph 24(1), Schedule 4 – Matters to be considered when issuing directions in respect of pharmacy premises core opening hours.
- 3.13 **Paragraph 24(1)(a) - are the proposed core opening hours such as to maintain as necessary the existing level of service provision for the people in the area of the pharmacy, or other likely users of the pharmacy premises?**
- 3.14 **1. What is the existing level of service provision?**
- 3.15 The applicant's current and proposed core hours of the pharmacy premises are as follows.
- 3.16 Current Opening Hours

Current										40:00	0:00
	S1		C1		S2		C2		S3		C3
Monday			9:00	13:00			13:00	17:00			
Tuesday			9:00	13:00			13:00	17:00			
Wednesday			9:00	13:00			13:00	17:00			
Thursday			9:00	13:00			13:00	17:00			

Friday			9:00	13:00			13:00	17:00				
Saturday												
Sunday												

3.17 Proposed Opening Hours

Opening Hours											40:00	0:00
	S1		C1		S2		C2		S3		C3	
Monday			13:30	21:30								
Tuesday			13:30	21:30								
Wednesday			13:30	21:30								
Thursday			13:30	21:30								
Friday			13:30	21:30								
Saturday												
Sunday												

3.18 The pharmacy does not provide Advanced services.

3.19 The applicant proposes to maintain opening for 40 core hours per week Monday to Friday, however they are requesting to open from 13:30 – 21:30.

3.20 **2. Is it necessary to maintain the existing level of service provision?**

3.21 The Committee noted the applicant provided the following information:

3.21.1 *“As medino is an online pharmacy, the change in core hours will not affect our existing level of service nationwide. In fact, this change is likely to improve service due to an additional Royal Mail collection at 21:00, complementing the existing 17:00 collection”.*

3.22 The Committee agreed, as there was no information submitted that evidenced pharmaceutical services were not utilised during the times that the applicant proposed to remove the core hour provision, it concluded that it was necessary to maintain the existing level of service provision.

3.23 **3. Will the applicant’s proposed core opening hours maintain the existing level of service provision at the pharmacy premises?**

- 3.24 The Committee agreed, they could not be satisfied the applicant's proposed core opening hours would maintain the existing level of service provision at the pharmacy premises, as there was no information submitted that evidenced this.
- 3.25 **4. Would the existing level of service provision be maintained by virtue of the existence of other pharmacies in the area at times when the applicant is proposing to close?**
- 3.26 The Committee noted the applicant provided no information regarding the existence of other pharmacies in the area at times when the applicant is proposing to close.
- 3.27 The Committee noted the applicant has not provided any information regarding the provision of advanced and enhanced services by the nearest pharmacies.
- 3.28 Taking into account that the applicant has not provided any evidence regarding the provision of pharmaceutical services during core opening hours by other pharmacies in the area, the Committee was not satisfied that patients would be able to access services from alternative pharmacies if the application is granted, and therefore it assumed that the existing level of service provision cannot be maintained by those other pharmacies.
- 3.29 The Committee agreed, as the applicant did not provide any evidence, maintaining the existing level of service provision was necessary, therefore paragraph 24(1)(a), part 3 of schedule 4 was not relevant. Consideration was therefore to be given to whether or not maintaining the existing level of service provision is not a realistically achievable outcome.
- 3.30 **Paragraph 24(1)(b), Schedule 4 - are the proposed core opening hours such as to maintain a sustainable level of adequate service provision for the people in the area of the pharmacy 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?**
- 3.31 The Committee noted the applicant is an online pharmacy and the change in core hours will not affect existing level of service nationwide, however according to the existing regulation, the applicant is obligated to provide any information to demonstrate that maintaining the existing level of service provision was not a realistically achievable outcome.
- 3.32 The Committee agreed the applicant did not provide any evidence to support this provision, the Committee was not satisfied as to whether the proposed core opening hours are such as to maintain a sustainable level of adequate service provision for the people in the area of the pharmacy or other likely users of the pharmacy premises in circumstances where maintaining the existing level of service provision is not a realistically achievable outcome.
- 3.33 **Decision**
- 3.34 The Committee refused the application.
- 3.35 Taking all the above information into account, the Committee were not satisfied that the proposed core hours of opening:
- 3.35.1 would maintain as necessary the existing level of service provision for the people in the area of the applicant's pharmacy premises, or other likely users of the pharmacy premises.

- 3.35.2 would maintain a sustainable level of adequate service provision for the people in the area of the applicant's pharmacy premises, 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.
- 3.36 The rationale for the Committee's decision is as follows:
- 3.36.1 The applicant did not provide information/evidence to support that other local pharmacies would be able to maintain the existing level of service provision when the applicant was proposing to close.
- 3.36.2 The applicant did not provide details around who is using the service, what services they required, and whether there would be any impact on patients should the hours change.
- 3.37 The Committee agreed that Medino Online Ltd has the right of appeal.
- 3.38 You have the right of appeal to the Secretary of State against our decision. Should you choose to appeal, then you should send in writing a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this letter to:
- 3.39 nhsr.appeals@nhs.net or
- 3.40 NHS Resolution, 8th Floor, 10 South Colonnade, Canary Wharf, London, E14 4PU"

4. The Appeal

In a letter to NHS Resolution dated 18 February 2025 the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

- 4.1 **"I am writing to formally appeal the decision to refuse our application to adjust our core NHS opening hours at Medino Online Ltd. While I understand the Committee's concerns regarding maintaining pharmaceutical service levels, I believe the decision does not take into account the specific nature of a Distance Selling Pharmacy (DSP) and how these changes would, in fact, improve our service delivery.**
- 4.2 **1. Nature of Our Pharmacy & Patient Impact**
- 4.3 **Medino is a distance selling pharmacy, meaning we provide services to patients across England, rather than focusing on a local patient base. Our NHS prescription volume is currently 20–30 prescriptions per month, serving patients from various regions in England.**
- 4.3.1 As per distance selling pharmacy regulations, we cannot allow patient collection from our premises, meaning any local patient impact is non-existent.
- 4.3.2 The proposed shift in hours does not change our total core hours but simply redistributes them more effectively to match operational needs.
- 4.4 **Given this, the assertion that changing our core hours would impact the "existing level of service provision" is not applicable, as our patient base is national, not local.**
- 4.5 **2. Regulatory Compliance & Service Continuity**

- 4.5.1 There will always be a pharmacist on the premises during the revised hours to provide both NHS and private services, ensuring full compliance with regulations.
- 4.5.2 DSP regulations do not require us to operate with the same considerations as a brick-and-mortar community pharmacy, as patient access is remote, and services are provided through home delivery and consultation, not walk-ins.
- 4.5.3 The shift in hours would enable better resource allocation, allowing us to maintain and even improve our service by aligning staff availability with patient demand.
- 4.6 **3. Reason for Requested Change**
- 4.7 **The original request for 9:00–17:00 hours was made by the previous superintendent pharmacist. Since then, our operational needs have changed, and keeping a pharmacist present during the early hours with little to no demand is not financially sustainable. Our workload is more efficiently managed between 13:30–21:30, and adjusting our hours accordingly would:**
 - 4.7.1 Eliminate unnecessary pharmacist presence during low-demand hours, reducing financial strain.
 - 4.7.2 Enhance operational efficiency by aligning resources with demand.
 - 4.7.3 Improve service reliability by accommodating an extra Royal Mail collection at 21:00, ensuring faster prescription dispatch.
- 4.8 **4. Lack of Evidence Requirement**
- 4.9 **The Committee has requested evidence to justify that the change will not affect service provision. However, given that:**
 - 4.9.1 No local patients rely on in-person service at our pharmacy.
 - 4.9.2 There is no physical patient access to our premises.
 - 4.9.3 Service levels would remain unchanged or even improve.
- 4.10 **It is common sense that our service provision will remain unaffected. The refusal to approve this change on the basis of a lack of evidence is therefore unreasonable, as no such evidence could logically exist for a DSP model that inherently does not rely on patient walk-ins.**
- 4.11 **Request for Review**
- 4.12 **Given the above, I respectfully request that the Committee reconsiders its decision and approves the proposed core hours change. This adjustment is practical, compliant with DSP regulations, and beneficial for both operational efficiency and patient service.**
- 4.13 **Please let me know if any additional information is required. I appreciate your time and consideration.”**

5. Representations

In a letter to NHS Resolution dated 27 February 2025 the Commissioner stated:

- 5.1 “Please note that from the 01 April 2023, community pharmacy contracting and commissioning has been delegated to Integrated Care Boards (ICBs). Hertfordshire and West Essex (HWE) ICB are hosting the function on behalf of the six East of England ICBs. The six ICBs have formed one Pharmaceutical Services Regulations Committee (PSRC) which is also hosted by HWE ICB.
- 5.2 Having reviewed the grounds of the appeal and the information provided by [XXX], Superintendent Pharmacist, on behalf of Medino Online Ltd (the Appellant), we remain of the opinion that this application should be refused.
- 5.3 The grounds for the appeal appear to be that the ICB did not take into account the specific nature of a Distance Selling Pharmacy (DSP).
- 5.4 Having reviewed the notice of appeal, HWE ICB would like to make the following representations on behalf of Bedfordshire, Luton and Milton Keynes ICB.
- 5.5 As the Appellant submitted an application to make a permanent change to core hours, the Pharmaceutical Services Regulations Committee (PSRC) considered this application under paragraphs 24 and 26, Schedule 4 of the Regulations
- 5.6 **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) 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).*
- 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 at 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.*
- 5.7 The current and proposed core hours are set out below:
- 5.8 Current [see table at 3.16]
- 5.9 Proposed [see table at 3.17]

- 5.10 The overall effect of the application is that the Appellant is seeking to redistribute their core hours Monday to Friday resulting in later opening times of 13:30 – 21:00.
- 5.11 NHS England's template application form asks that the applicant provide such information so as to demonstrate that the proposed core opening hours will either:
- 5.11.1 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
- 5.11.2 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.
- 5.12 In response, the Appellant stated '*As medino is an online pharmacy, the change in core hours will not affect our existing level of service nationwide. In fact, this change is likely to improve service due to an additional Royal Mail collection at 21:00, complementing the existing 17:00 collection*'.
- 5.13 On appeal the Appellant has expanded upon this, and this information can be found in **Appendix 1**.
- 5.14 The PSRC has reviewed this additional information and maintains that the decision to refuse the application was correct.
- 5.15 **Paragraph 24(1)(a), Schedule 4**
- 5.16 It is first necessary to identify the existing level of service provision for people in the area of Medino Online Ltd or other likely users of the pharmacy.
- 5.17 The Appellant is proposing to redistribute the 40 core hours by changing their opening times to later in the day i.e. 13:30 – 21:30.
- 5.18 There is no evidence that the pharmacy is not being used during the times that the Appellant is proposing to remove the core hours provision. The existing level of service provision would therefore not be maintained.
- 5.19 It is therefore necessary to identify whether there are other providers of pharmaceutical services in the area, when they are open and whether when considered, they would maintain the existing level of service provision.
- 5.20 The Appellant provided no information regarding the existence of other pharmacies in the area at times when the applicant is proposing to close i.e. 09:00 – 13:30.
- 5.21 On appeal the Appellant states '*Medino is a distance selling pharmacy, meaning we provide services to patients across England, rather than focusing on a local patient base. Our NHS prescription volume is currently 20–30 prescriptions per month, serving patients from various regions in England.*
- 5.21.1 *As per distance selling pharmacy regulations, we cannot allow patient collection from our premises, meaning any local patient impact is nonexistent.*
- 5.21.2 *The proposed shift in hours does not change our total core hours but simply redistributes them more effectively to match operational needs.*

- 5.22 *Given this, the assertion that changing our core hours would impact the "existing level of service provision" is not applicable, as our patient base is national, not local.'* (point 1, appeal letter)
- 5.23 The Appellant also states:
- 5.23.1 *There will always be a pharmacist on the premises during the revised hours to provide both NHS and private services, ensuring full compliance with regulations.*
- 5.23.2 *DSP regulations do not require us to operate with the same considerations as a brick-and-mortar community pharmacy, as patient access is remote, and services are provided through home delivery and consultation, not walk-ins.*
- 5.23.3 *The shift in hours would enable better resource allocation, allowing us to maintain and even improve our service by aligning staff availability with patient demand.*
- 5.23.4 (point 2, Appeal letter)
- 5.24 PSRC notes that the same test applies to applications from DSPs wishing to change their core opening hours. The test does not differentiate between a DSP and a 'bricks and mortar' pharmacy, even though the former cannot provide essential services face to face at the pharmacy premises and is required to provide such services to anyone, anywhere in England who requests them. The PSRC also notes that in considering the application, it is required to look wider than dispensing services and review *all* essential services and any advanced and enhanced services that the applicant may provide.
- 5.25 Consequently, it is the view of the PSRC that the proposed core opening hours do not satisfy paragraph 24(1)(a), Schedule 4.
- 5.26 **Paragraph 24(1)(b), Schedule 4**
- 5.27 As the PSRC remains of the opinion that:
- 5.27.1 it is necessary to maintain the existing level of service provision,
- 5.27.2 the Appellant's proposed opening hours would not achieve that, and
- 5.27.3 there is no evidence that other providers of pharmaceutical services would maintain the existing level of service provision,
- 5.28 the PSRC now considers paragraph 24(1)(b), Schedule 4 with regard to the Appellant's representations.
- 5.29 PSRC notes that the Appellant states the reason for the requested change as follows:
- 5.30 *'The original request for 9:00–17:00 hours was made by the previous superintendent pharmacist. Since then, our operational needs have changed, and keeping a pharmacist present during the early hours with little to no demand is not financially sustainable. Our workload is more efficiently managed between 13:30–21:30, and adjusting our hours accordingly would:*
- 5.30.1 *Eliminate unnecessary pharmacist presence during low-demand hours, reducing financial strain.*
- 5.30.2 *Enhance operational efficiency by aligning resources with demand.*

5.30.3 *Improve service reliability by accommodating an extra Royal Mail collection at 21:00, ensuring faster prescription dispatch.'*

5.30.4 (point 3, Appeal letter)

5.31 The Appellant has not provided any evidence to demonstrate that the current users of Medino Online Ltd who can access services from 09:00 – 17:00 Monday to Friday would not be affected should the change in hours be granted. In light of this, it has to be considered that the service is necessary.

5.32 The PSRC is not persuaded by the Appellant's representations that there are any circumstances where maintaining a sustainable level of adequate service provision for people in the area or other likely users of the pharmacy is either unnecessary or not a realistically achievable outcome. As identified above in point 3 of the Appeal letter, the Appellant states that adjusting their hours would eliminate '*unnecessary pharmacy presence during low-demand hours, reducing financial strain*'. Whilst PSRC can empathise with the challenges and cost pressures facing community pharmacy, the Appellant has not provided any evidence to support this statement.

5.33 Consequently, the PSRC is of the view that the proposed core opening hours do not satisfy paragraph 24(1)(b), Schedule 4 and remains of the opinion that the application should be refused."

6. Observations

No observations were received in response to the Commissioner's representations.

7. Consideration

7.1 I note the following:

7.1.1 The Applicant's core opening hours total 40 hours and the Applicant proposes to redistribute those 40 core opening hours pursuant to paragraph 26 of Schedule 4.

7.1.2 The Applicant wishes to open between 13:30 and 21:30 Monday to Friday, rather than between 9:00 and 17:00.

7.1.3 The Applicant is closed on Saturday and Sunday.

7.2 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.

7.3 Paragraph 26(1) states:

"26.— (1) An NHS pharmacist (P) may apply to NHS England 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."

7.4 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 NHS England with such information as NHS England may reasonably request in respect of the matters that NHS England must seek to ensure pursuant to paragraph 24(1).

7.5 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 at 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.*

7.6 Paragraph 24(2) states:

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

- (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.*

7.7 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 24(1)(b) if that is required.

7.8 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.

7.9 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.

7.10 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.

- 7.11 I note that other than the Applicant's own core hours provision, no indication has been given of the existing level of service provision in the area.
- 7.12 I note the Applicant's comments that "*As per distance selling pharmacy regulations, we cannot allow patient collection from our premises, meaning any local patient impact is non-existent*" and "*... the assertion that changing our core hours would impact the "existing level of service provision" is not applicable, as our patient base is national, not local.*"
- 7.13 In considering whether it is necessary to maintain the existing level of service provision, I note that the Applicant is not looking to reduce the number of hours each week that services are provided. Therefore from a pure "number of hours of service provision each week" perspective, the existing level of service provision is maintained such that consideration of whether it is necessary to maintain the level of service provision is not needed.
- 7.14 However, the Applicant is applying to change the times that services are provided meaning that they will no longer be providing services on weekday mornings. 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 it is maintained.
- 7.15 To determine whether it is necessary to maintain the existing level of service provision, I would usually expect to see some information concerning those using the pharmacy and at what times they are accustomed to doing so. Then, if I were 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.
- 7.16 I note that I have not been provided with any information in this regard. 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.
- 7.17 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.
- 7.18 I note that paragraph 24(1)(a) can be considered as having two separate elements of service that need to be maintained, this is "*service provision for people in that area*" and "*likely users of the pharmacy premises*". As such, in determining whether the change will maintain the existing level of service the Applicant must be able to demonstrate that neither aspects will be impacted.
- 7.19 I am mindful that the Applicant is a distance selling pharmacy and therefore there is no face to face contact permitted as set out in the Regulations and as a condition of the grant of the application. The Applicant has explained that since they cannot allow patient collection from the premises, then local patient impact is non-existent. However, I have not been provided with any explanation as to how this logic holds for both of the elements I have identified. I consider that the fact that patients cannot access the premises could mean that there are no "likely users of the pharmacy premises".

- 7.20 Nonetheless, I note the Commissioner's comment that "... in considering the application, it is required to look wider than dispensing services and review all essential services and any advanced and enhanced services that the applicant may provide." This is relevant as distance selling pharmacies are permitted to provide advanced and enhanced service at the pharmacy premises, provided this is done in accordance with the Regulations. However, I note the Commissioner's confirmation in its decision that the Applicant does not provide any advanced services. Whilst there are no comments as to enhanced services, I consider that the Applicant's general stance, and lack of objection on this point by the Commissioner, sufficient to allay any concerns I have in this regard. I consider, therefore, that there are no users of the pharmacy premises.
- 7.21 I will next consider the level of service provision for people in the area. I note that the Applicant is a distance selling pharmacy and, therefore, provides services nationally. It is therefore possible that services are provided to local users, via delivery. As I have noted, the Applicant has not provided any information regarding its provision of services to local users. I must infer that there is some level of local provision, as I have not been provided with any evidence to the contrary. As such, I consider that the Applicant must evidence that, despite the changes, the existing level of service provision will be maintained for people in the area in which the premises are located.
- 7.22 I note that the Applicant has provided only a limited explanation as to why service levels would be maintained. The Applicant has stated that service levels would remain unchanged or even improved but has not expanded on these points. The Applicant has also stated that there will be an additional Royal Mail collection at 21:00 and that there is an existing 17:00 collection. However, I am mindful of the fact that I have been provided no other information as regards if there are other existing collections or how the current system operates. I have also not been provided the information which supports these assertions or would allow me to effectively evaluate their veracity.
- 7.23 I note that as per paragraph 26(2) of Schedule 4 of Regulations, it is for the Applicant to provide such information as the Commissioner requests in relation to the matters it must ensure under paragraph 24(1). The application form required the Applicant to provide information that demonstrated that their proposed core opening hours would:
- "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."*
- as per paragraph 2 above. I consider this to be the information requested by the Commissioner and hence needed to be provided by the Applicant.
- 7.24 I consider the information which was provided is insufficient in order for me to evaluate whether services are going to be maintained in the area, and only suitable to establish that likely users of the pharmacy premises would not be impacted, as they did not exist.
- 7.25 I consider that simply asserting that services will not be impacted, or improved, is not the same as providing information to satisfy the requirements. In order for the Commissioner to evaluate any impact, the Applicant needed to provide evidence and an explanation. I consider that it has not done so.
- 7.26 Based on the lack information provided, I am therefore not satisfied that the existing level of service provision would be maintained by virtue of the number of hours provided being maintained, on the same days, albeit at different times.

7.27 Under paragraph 26(10) “The Secretary of state may, when determining an appeal, either confirm the action taken by NHS England or take any action that the NHS England could have taken under sub-paragraph (4)”.

7.28 Paragraph 26(4) states:

(4) When it determines the application, NHS England must –

(a) 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 under this paragraph or granting it only in part;

(b) confirm any existing direction in respect of the times at which P must provide pharmaceutical services at the pharmacy premises, provided that the existing direction (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations) would meet the requirements of sub paragraph (5) and (6); or

(c) either –

(i) revoke, without replacing it, any existing direction in respect of the times at which P must provide pharmaceutical services at the pharmacy premises (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations), where this has the effect of granting the application under this paragraph or granting it only in part, or

(ii) in a case where there is no existing direction, issue no direction.

7.29 With regard to paragraph 26(4)(a) I note that a direction is not in place for the Applicant to provide 40 core hours as it was, and remains, a condition on inclusion for the Applicant to provide those hours. This is also confirmed by the Commissioner in its decision report.

7.30 For the above reasons, I am not confirming any existing direction in line with paragraph 26(4)(b).

7.31 Further, there is no direction to revoke in line with paragraph 26(4)(c).

7.32 The only option left to me is therefore to confirm the decision of the Commissioner to reject the change of hours application, without a direction.

8. Determination

8.1 Based on the information provided, I am not satisfied that the pharmaceutical services provision that would result from the Applicant's proposed hours would maintain as necessary the existing level of service provision for the people in that area or other likely users of the pharmacy premises.

8.2 Therefore I confirm the decision of the Commissioner to reject the change of hours application.

**Head of Appeals
NHS Resolution**