

14 March 2025

REF: SHA/ 26423

**APPEAL AGAINST HERTFORDSHIRE AND WEST
ESSEX ICB DECISION REGARDING A BREACH NOTICE
AT FM MEDICO LTD, 7 HOWARD DRIVE,
BOREHAMWOOD, HERTFORDSHIRE, WD6 2NY**

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

Tel: 020 3928 2000
Email: nhsr.appeals@nhs.net

1 Outcome

- 1.1 Pursuant to paragraph 9(5)(a) of Schedule 3 to the Regulations, I confirm the decision of the Commissioner.

A copy of this decision is being sent to:
FM Medico Ltd
Hertfordshire and West Essex ICB

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1 The Breach Notice

A Breach Notice dated 25 November 2024 was sent to FM Medico Ltd (“the Appellant”) in respect of 7 Howard Drive, Borehamwood, Hertfordshire, WD6 2NY. The Breach Notice stated:

- 1.1 “I am writing to inform you that the ICB Pharmaceutical Services Regulatory Committee (PSRC) met on Wednesday 6 November 2024, where it was made aware of the failure of F M Medico to notify the ICB of a change in Superintendent within 30 days.
- 1.2 The decision was made by the PSRC, in line with your Terms of Service, Schedule 4, paragraph 32(3), and paragraph 32(4), that the attached Breach Notice be served.
- 1.3 **Breach notice – Failure to notify of change(s) of director and/or superintendent**
- 1.4 **Name of contractor: F M Medico Ltd**
- 1.5 **Address of premises: 7 Howard Drive, Borehamwood, Hertfordshire WD6 2NY**
- 1.6 **Date of inclusion in the pharmaceutical list for the area of Hertfordshire Health and Wellbeing Board: 31 July 2006.**
- 1.7 **This is a breach notice issued under regulation 71 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the 2013 regulations).**
- 1.8 **Nature of the breach**
- 1.9 Under paragraph 32(3), Schedule 4 of the 2013 regulations a body corporate that is included in one or more pharmaceutical lists is required to give notice to NHS England within 30 days (or if this is impracticable, as soon as practicable thereafter) of any changes to the:
 - 1.9.1 names of its directors, and
 - 1.9.2 name or address of its superintendent.
- 1.10 Under paragraph 32(4), Schedule 4 if a body corporate that is included in one or more pharmaceutical lists appoints a new superintendent or director it must, within 30 days of the person’s appointment, supply the required fitness information to NHS England on that person.
- 1.11 NHS England has determined that such notifications and the required fitness information are to be provided to Primary Care Support England (PCSE).

- 1.12 Since 1 April 2024 [sic], NHS England has delegated the commissioning of pharmaceutical services to integrated care boards (ICBs). ICBs are therefore responsible for considering the notifications of changes of directors and/or superintendent and accompanying fitness information and determining whether bodies corporate remain fit and proper persons following such changes.
- 1.13 NHS Herts and West Essex Integrated Care Board has become aware that [RK] was appointed as the superintendent in April 2024.
- 1.14 NHS Herts and West Essex Integrated Care Board contacted you on 25 September 2024 for an explanation as to why the notification and required fitness information were not sent to PCSE. Emails were sent to [redacted by NHSR].
- 1.15 Mr. M, Director of F M Medico Ltd, advised that this was an oversight, they submitted information to the GPhC but recognised the commissioner should have been informed but nothing was sent.
- 1.16 The Pharmaceutical Services Regulations Committee (PSRC) considered the above and is satisfied that F M Medico Ltd:
- 1.16.1 have failed to notify PCSE of the change of superintendent within 30 days of their appointment, and
- 1.16.2 have failed to provide the required fitness information on them within 30 days.
- 1.17 As the regulatory 30 days have passed, you cannot remedy this breach and therefore the PSRC has decided that it is appropriate to issue this breach notice.
- 1.18 You are required not to repeat the breach again.
- 1.19 You have a right of appeal to the Secretary of State against the issuing of this breach notice.
- 1.20 Should you choose to appeal then you should send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this notice to nhsr.appeals@nhs.net or:
- 1.21 Primary Care Appeals
NHS Resolution
8th Floor
10 South Colonnade
Canary Wharf
London
E14 4PU
- 1.22 Please note that should you fail to comply with the requirements of this breach notice we reserve the right to exercise our powers to take further action in relation to your inclusion in the pharmaceutical list in respect of the above named legal entity. This may include removal of premises from the relevant pharmaceutical list under regulation 73 of the 2013 regulations.
- 1.23 Under paragraph 35(4), Schedule 4 of the 2013 regulations F M Medico submitted the information mentioned in paragraphs 3 and 4, Schedule 2 of the regulations on the new superintendent to PCSE dated 26 September 2024.

- 1.24 NHS Herts and West Essex Integrated Care Board will determine, at the PSRC on 18 December 2024, whether F M Medico Ltd remains a fit and proper person to be included in the pharmaceutical list for the Hertfordshire health and wellbeing board.”

2 The Appeal

In a letter dated 17 December 2024 addressed to NHS Resolution, the Appellant appealed against Hertfordshire and West Essex ICB’s (“the Commissioner”) decision. The grounds of appeal are:

- 2.1 “I am writing in response to the Hertfordshire and West Essex ICB’s (ICB) letter dated 25 November 2024 comprising the breach notice of the same date in respect of F M Medico Ltd’s (FM Medico) NHS contract, citing the failure to give the NHS England notice within 30 days of a change to the superintendent.
- 2.2 As previously advised to the ICB, the matter was an oversight, as although the change of superintendent information was submitted to the GPhC, there was miscommunication between FM Medico and [RK] as to which party would be submitting the change of superintendent form.
- 2.3 We affirm that, notwithstanding this oversight, we are aware of our obligations under Schedule 4 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 to notify NHS England within 30 days of the change of superintendent.
- 2.4 We can further confirm:
- 2.4.1 that this type of oversight will not be repeated again;
- 2.4.2 that there is and always has been a superintendent pharmacist in place without interruption at the pharmacy; and
- 2.4.3 FM Medico can confirm that there has been no harm to patients and that patient care has not been compromised as a result of the miscommunication.
- 2.5 We note the ICB will determine on 18 December 2024 whether FM Medico remains fit and proper to be included in the pharmaceutical list for the Hertfordshire Health and Wellbeing Board.
- 2.6 FM Medico is happy to provide any further information that the ICB requires and please continue to communicate with myself by email on [redacted by NHSR].”

3 Summary of Representations

This is a summary of representations received on the appeal.

- 3.1 The Commissioner
- 3.1.1 “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.
- 3.1.2 Please find below information we wish to be considered in relation to FM Medico Ltd (the Appellant). Having reviewed the letter of appeal from [MM] on

behalf of the Appellant, we remain of the opinion that the issuing of a breach notice was correct.

- 3.1.3 The grounds for the appeal appear unclear as the Appellant acknowledges that the commissioner was not notified of a change in superintendent within 30 days. The required fitness information was therefore not provided. The Appellant explains that this was an oversight:

3.1.3.1 *“there was miscommunication between FM Medico and [RK] as to which party would be submitting the change of superintendent form.”* (Letter of appeal, page 1).

- 3.1.4 There appears to be no dispute that a breach of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations) has taken place. Under paragraph 32(3), Schedule 4 of the Regulations, a body corporate that is included in one or more pharmaceutical lists is required to give notice to NHS England/ICB within 30 days (or if this is impracticable, as soon as practicable thereafter) of any changes to the:

3.1.4.1 names of its directors, and

3.1.4.2 name or address of its superintendent.

- 3.1.5 Under paragraph 32(4), Schedule 4 if a body corporate that is included in one or more pharmaceutical lists appoints a new superintendent or director it must, within 30 days of the person's appointment, supply the required fitness information to NHS England/ICB on that person.

- 3.1.6 FM Medico should therefore have notified the ICB of the change in superintendent and provided the relevant fitness information within 30 days.

- 3.1.7 As part of dispute resolution, Mr M was contacted and asked to confirm why the ICB was not notified. Mr M confirmed that *“the change in superintendent information was submitted to the GPhC”* (Letter of appeal, page 1). Mr M then explains the oversight as referenced earlier in this letter. This email exchange can be viewed within the extract of the Committee Report presented to the Pharmaceutical Services Regulations Committee (PSRC) and enclosed with these representations. Also enclosed is an extract from the minutes of the PSRC meeting and a copy of the breach notice.

- 3.1.8 The Appellant notes in their letter of appeal that they can confirm that *“the oversight”* will not happen again. The ICB can confirm that the breach notice outlines the requirement not to repeat the breach.

- 3.1.9 The Appellant also states that there *“always has been a superintendent in place....”* (Letter of appeal, page 2). The ICB notes that whilst there may have been a superintendent, this does not negate the regulatory requirement to inform the ICB of a change in superintendent and provide the required fitness information.

- 3.1.10 The Appellant states that *“there has been no harm to patients and that care has not been compromised as a result of the miscommunication.”* (Letter of appeal, page 2) There are currently no known cases of patient harm however again, this does not negate the need to notify the ICB and provide the relevant fitness information. As a result of not being notified of a change in

superintendent, the ICB has a body corporate on the pharmaceutical list who we cannot be assured are fit and proper.

- 3.1.11 The ICB remains of the opinion that there has been a breach of paragraph 32(3) and 32(4) Schedule 4. The ICB were correct in issuing the breach notice."

Extract from Committee Report for PSRC on 6 November 2024. NHS Resolution should note this is an extract from the Committee report relating to request to issue a breach notice to FM Medico Ltd - this formed part of a wider issues being considered in relation to FM Medico Ltd.

- 3.1.12 "FM Medico Ltd

- 3.1.13 FM Medico Ltd are the legal entity on the pharmaceutical list for the area of Hertfordshire HWB. There is one active director for the company Mr [MM]. According to records held by the Pharmacy and Optometry Team (P&O team) [PF] was the superintendent (SI) at FM Medico Ltd. The SI working in the pharmacy and recorded on the GPhC register is [RK]. It is understood that [RK] was appointed in April 2024 but the required notification and fitness forms for [RK] were not submitted by FM Medico Ltd within 30 days in line with the NHS Pharmaceutical and Local Pharmaceutical Services Regulations 2013, as amended (the Regulations).

- 3.1.14 On 25 September 2024, Mr M was contacted by the P&O team to remind him of the regulations and the requirement to submit the fitness forms. Mr M was asked why he failed to inform the ICB of a change of SI within 30 days. Mr M advised that this was an oversight, they submitted information to the GPhC but recognised the commissioner should have been informed but nothing was sent: [see below].

- 3.1.15 PSRC is asked to consider whether it wishes to issue a breach notice to FM Medico Ltd for failing to notify the ICB of a change in SI and provide the relevant fitness information within 30 days.

- 3.1.16 Mr M has confirmed that the notification and forms for [RK] have now been submitted to PCSE. A Committee Report was requested on 4 October 2024, received on 21 October 2024. The Committee report will now be processed, reviewed by a clinical advisor, and is anticipated to be determined at the PSRC scheduled for 27 November 2024."

Extract from the minutes from PSRC on 6 November 2024. NHS Resolution should note this is an extract from the minutes relating to the breach notice for FM Medico Ltd - this formed part of a wider issues being considered in relation to FM Medico Ltd:

- 3.1.17 "The legal entity on the pharmaceutical list for Village Pharmacy is FM Medico Ltd. There is one active director for the company Mr [MM] who confirmed in September 2024 that he sold the business in April 2024. MM advised that a management company is running the pharmacy called "Since 1814 Limited." Whilst a Change of Ownership has been submitted by Since 1814 Ltd for 7 Howard Drive, Borehamwood, WD6 2NY it has not been determined.

- 3.1.18 According to records held by the Pharmacy and Optometry Team (P&O team) [PF] was the SI at FM Medico Ltd. The SI working in the pharmacy and recorded on the GPhC register is [RK]. It is understood that RK was appointed in April 2024 but the required notification and fitness forms for RK were not submitted by FM Medico Ltd within 30 days in line with the Regulations.

- 3.1.19 The Committee noted that MM was asked why this was not completed as part of local dispute resolution and MM attributed this to an oversight and the forms were later submitted.
- 3.1.20 The Committee were asked to consider whether it wanted to issue a breach notice to FM Medico Ltd for failing to notify the ICB of the SI change and failing to submit the required fitness information within the required timeframe. It was agreed that a breach should be issued.”
- 3.1.21 End.”

Email of 25 September 2024 from the Commissioner to the Appellant

- 3.1.22 “According to our pharmaceutical list, [PF] is the current Superintendent (SI) of F M Medico Ltd. We believe that [RK] was appointed as SI in April 2024. We are unable to verify that F M Medico Ltd has submitted the Change in Director and/or Superintendent form to notify us of this change.
- 3.1.23 Any changes to Directors or Superintendent Pharmacist must be notified to NHSCB as per regulations highlighted below:

The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

Schedule 4 Terms of Service

Part 4

Other information to be supplied

32.—(1) An NHS pharmacist (P) must give notice to the NHSCB within 30 days (or if this is impracticable, as soon as practicable thereafter) of—

(a) any occurrence requiring a change in the information recorded about P in the pharmaceutical list which P has not otherwise notified to the NHSCB in accordance with these Regulations;

(b) if P is an individual, any change to P’s private address;

(c) if P is a body corporate, any change to the name, registration number, registered office or telephone number relating to that office of the body corporate; and

(d) any occurrence requiring P’s addition to or removal from an EPS list or a change in the information recorded about P in that list.

(2) P must give the NHSCB, if it so requests, the name of any pharmacist employed or engaged by P who is responsible for dispensing a particular prescription.

(3) If P is a body corporate, it must give notice to the NHSCB within 30 days (or if this is impracticable, as soon as practicable thereafter) of any changes to—

(a) the names of its directors; and

(b)the name or address of its superintendent.

(4) If P is a body corporate and appoints a superintendent or director who was not listed on P's application for inclusion on a pharmaceutical list, P must, within 30 days of the person's appointment, supply to the NHSCB the information mentioned in paragraph 3 and 4 of Schedule 2 about that person.

(5) If P or a director or superintendent of P (if P is a body corporate) is on, or is a director or superintendent of a body corporate which is on, a relevant list other than a pharmaceutical list held by the NHSCB, they must supply in writing to the NHSCB—

(a)in the case of a director or superintendent of a body corporate, the name and registered office of the body corporate on the other relevant list; and

(b)particulars of the other relevant list.

(6) P or the director or superintendent of P (if P is a body corporate) must inform the NHSCB if they, or a body corporate of which they are a director or superintendent, apply to be included in a relevant list of another primary care organisation, and of the outcome of any such application.

3.1.24 F M Medico Ltd is required to submit a change of Director and/or Superintendent form to PCSE within the next 2 weeks. ([Market Entry | PCSE \(england.nhs.uk\)](https://www.marketentry.nhs.uk/)). If we are not notified of the change in SI, a report will be taken to the Pharmaceutical Services Regulation Committee to decide on next steps.

3.1.25 Please can you explain why F M Medico Ltd did not inform the ICB of the change in SI.”

Email of 30 September 2024 from the Appellant to the Commissioner

3.1.26 “Further to your below email. When the transaction was completed in April the purchasers previous manager had filled the charge of ownership application which was submitted. It seems that there was confusion in that the new superintendent details were included in that application and it was assumed that this would also cover the interim period. However I agree that even though the GPhC SI change was submitted but I realise that the NHSE SI change should also have been sent. Apologies for this oversight which was missed during the changeover.

3.1.27 Please find attached a copy of the SI change application which has now been submitted.” [appendix A].

3.1.28 [A copy of the Breach Notice was also enclosed].

4 **Observations**

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

5 **Consideration**

- 5.1 Under Regulation 71(1) “Breaches of terms of service: breach notices” of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the Regulations”), a Breach Notice may be issued:

71. (1) Where an NHS chemist (C) breaches a term of service and the breach is not capable of remedy, NHS England may by a notice (“a breach notice”) require C not to repeat the breach.

- 5.2 I note that in the Regulations an NHS Chemist means “an NHS appliance contractor or an NHS pharmacist”. An NHS pharmacist is defined as “a person included in a pharmaceutical list of the type referred to in regulation 10(2)(a);”. Regulation 10(2)(a) states:

10(2) “Those lists (which are pharmaceutical lists) are

(a) a list of persons who undertake to provide pharmaceutical services in particular by way of the provision of drugs;”

- 5.3 The Regulations contain no definition as to what constitutes a breach of terms of service which is not capable of remedy.

- 5.4 As a preliminary matter, I note the Appellant states that “*We note the ICB will determine on 18 December 2024 whether FM Medico remains fit and proper to be included in the pharmaceutical list for the Hertfordshire Health and Wellbeing Board.*” I note that no further information has been provided on this point to confirm whether the Appellant’s pharmacy is still included in the pharmaceutical list or not. I note that in the extract of minutes provided by the Commissioner, it states that “*MM advised that a management company is running the pharmacy called “Since 1814 Limited” and further that “whilst a Change of Ownership has been submitted by Since 1814 Ltd for 7 Howard Drive, Borehamwood, WD6 2NY it has not been determined.*” Therefore, without evidence to the contrary, I must consider that the Appellant’s pharmacy is included in the pharmaceutical list.

- 5.5 The Breach Notice was issued pursuant to Regulation 71(1) and is compliant with the requirements of a breach notice as it includes the nature of the breach and an explanation of the Appellant’s right of appeal under Regulation 77(1)(c).

- 5.6 I note in the Breach Notice there is reference to previous correspondence between the parties, copies of which are provided in the Commissioner’s representations. I further note that following this, the Commissioner issued the Breach Notice. I am therefore of the view that the Appellant had the opportunity to enter into local dispute resolution with the Commissioner. Given that both parties do not dispute that local dispute resolution has been exhausted I am content that I can deal with this matter.

- 5.7 The Appellant seeks to appeal against the decision of the Commissioner to issue the Breach Notice for its failure to notify the Commissioner of the change of its superintendent within 30 days of their appointment in accordance with paragraph 32(3) of Schedule 4 and failure to provide the required fitness information for them within 30 days in accordance with paragraph 32(4) of Schedule 4.

- 5.8 I note that paragraph 32(3) of Schedule 4 states:

(3) If P is a body corporate, it must give notice to NHS England within 30 days (or if this is impracticable, as soon as practicable thereafter) of any changes to—

the names of its directors; and

the name or address of its superintendent.

- 5.9 I note that paragraph 32(4) of Schedule 4 states:

32- Other information to be supplied

(4) If P is a body corporate and appoints a superintendent or director who was not listed on P's application for inclusion on a pharmaceutical list, P must, within 30 days of the person's appointment, supply to the NHS England the information mentioned in paragraph 3 and 4 of Schedule 2 about that person.

- 5.10 From the information provided, I note that there was a change of superintendent at the Appellant's pharmacy in April 2024, which subsequently came to the attention of the Commissioner in September 2024. I have had regard to the email of 25 September 2024 from the Commissioner to the Appellant and the Appellant's response by way of email dated 30 September 2024. I note that within this email, the Appellant provided the relevant form to the Commissioner which appears to be the information the Commissioner had requested. I further note that the Commissioner confirmed in the Breach Notice that *"F M Medico submitted the information mentioned in paragraphs 3 and 4, Schedule 2 of the regulations on the new superintendent to PCSE dated 26 September 2024"*. I am therefore of the view that the Commissioner now has the information it requested but if this is not the case, this is a matter for the Commissioner to consider.
- 5.11 I note the Appellant has acknowledged that its failure to provide the relevant information to the Commissioner was an *"oversight"* and does not dispute the fact that the information was not provided. I consider that the Regulations clearly envisage proactive provision of information by the Appellant within a set timescale and that this was not adhered to here. Given that the deadline to provide the information has now passed, while the information can still be provided (and appears to have been), it is not possible to remedy the failure to provide the information within the timescale (and I would note that provision of the information is not within 30 days of the request to provide it, rather it is within 30 days of the appointment of the superintendent/director).
- 5.12 I further note the Appellant's comment that *"there is and always has been a superintendent pharmacist in place without interruption"* and that *"there has been no harm to patients and that patient care has not been compromised as a result of the miscommunication"*. I also note the Commissioner's response to these points in its representations. I take the same view as the Commissioner. Despite these assurances, this does not negate the Appellant's responsibility in line with its Terms of Service.
- 5.13 Therefore, as a result of the Appellant's actions, I am of the view that this constitutes a breach of paragraph 32(3) and 32(4) of Schedule 4 to the Regulations. I am therefore satisfied that it was appropriate for the Commissioner to issue a Breach Notice to FM Medico Ltd.
- 5.14 I note that the Appellant has confirmed that it will not repeat the breach again which I note is a requirement within the Breach Notice, something which the Commissioner has commented on in its representations. I further note that the Commissioner has the jurisdiction to make this request in accordance with Regulation 71.

6 Decision

- 6.1 I am of the view that under NHS Resolution's powers, as set out in paragraph 9(5) of Schedule 3 to the Regulations, I may either confirm the decision of the Commissioner

or substitute for that decision any decision that the Commissioner could have taken when it took that decision.

- 6.2 Pursuant to paragraph 9(5)(a) of Schedule 3 to the Regulations, I confirm the decision of the Commissioner.

Head of Appeals
NHS Resolution