

2 February 2024

REF: SHA/26111

**APPEAL AGAINST NHS GREATER MANCHESTER
INTEGRATED CARE BOARD DECISION REGARDING A
BREACH NOTICE AT 14A WHITELEGGE STREET,
BURY BL8 1SW**

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

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

1 Outcome

- 1.1 Pursuant to paragraph 9(5)(b) of Schedule 3 to the Regulations, I substitute the decision of the Commissioner to issue the Breach Notice with the decision to issue a remedial notice with the same wording except for the changes below:
- 1.1.1 substitute all references to “breach notice” and “regulation 71” with reference to “remedial notice” and “regulation 70”; and
 - 1.1.2 substitute the requirement to not repeat the breach with the requirement to remedy the breach.

A copy of this decision is being sent to:

Kamm Trading Ltd
NHS Greater Manchester Integrated Care

Advise / Resolve / Learn

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1 The Breach Notice

A Breach Notice dated 5 October 2023 was sent to Kamm Trading Ltd (“the Appellant”) in respect of 14A Whitelegge Street, Bury BL8 1SW:

- 1.1 **“Name of contractor:** Kamm Trading Ltd (t/a Futurecare Pharmacy)
- 1.2 **Address of premises:** 14a Whitelegge Street, Bury, BL8 1SW
- 1.3 **Date of inclusion in the pharmaceutical list for the area of Bury Health and Wellbeing Board (HWB):** 30/09/2019
- 1.4 This is a breach notice issued under Regulation 71 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (“the Regulations”).
- 1.5 **Nature of the breach:**
- 1.6 NHS Greater Manchester Integrated Care (“NHS Greater Manchester”) manages NHS community pharmacy contracts under delegation from NHS England since 01/07/2022.
- 1.7 NHS Greater Manchester wrote to Kamm Trading Ltd (“the Contractor”) on 11/08/2023 (copy attached) and received a brief response the same day (11/08/2023) which did not satisfactorily address the actions identified in NHS Greater Manchester’s letter. The Contractor was informed by email on 14/08/2023 that the response received was insufficient, and that all actions identified in the letter still required completion by 25/08/2023 (i.e. 14 days from the date of NHS Greater Manchester’s letter).
- 1.8 The Contractor failed to acknowledge or respond within the 14 day deadline.
- 1.9 NHS Greater Manchester wrote to the Contractor again on 07/09/2023 to remind the Contractor that although the Registration Authority Team had visited the pharmacy site on 22/08/2023 and completed the actions relating to Smartcard access/training, there were still a number of actions from the original letter of 11/08/2023 outstanding. The Contractor was advised that the matter had been discussed at the Pharmaceutical Services Regulations Committee (PSRC)’s meeting on 31/08/2023 and a final deadline extension had been agreed for the Contractor to provide the requested written confirmation/evidence to demonstrate that all identified actions had been completed.
- 1.10 The Contractor again failed to acknowledge or respond within the extended deadline i.e. by 14/09/2023.
- 1.11 The matter was therefore referred back to the PSRC and was discussed at its meeting on 28/09/2023. Due to the failure of the Contractor to engage with the local dispute resolution process, the PSRC concluded that NHS Greater Manchester did not have

adequate assurances that the Contractor was compliant with its Terms of Service and authorised the issuing of this breach notice.

- 1.12 The Contractor is advised that Schedule 4, Part 4, Paragraph 35 of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations) states:

“Inspections and access to information

35(3) P must, at the request of the NHSCB or of X, allow it or X access to any information which it or X reasonably requires—

(a) for the purposes mentioned in sub-paragraph (1); or

(b) in the case of the NHSCB, in connection with its functions that relate to pharmaceutical services.”

- 1.13 (Please note that “P” is the Contractor, and “NHSCB” refers to the current commissioning body, NHS Greater Manchester).

- 1.14 It is considered that the Contractor is in breach of Schedule 4, Part 4, Paragraph 35(3)(b) as it has failed on two separate occasions to provide the requested information in response to NHS Greater Manchester’s letter of 11/08/2023. NHS Greater Manchester requires the requested information in order to ascertain whether the Contractor is aware of, and understands, its obligations relating to ongoing compliance with the Terms of Service.

- 1.15 The requirement to provide a response within the originally agreed timeframes cannot now be remedied as the final deadline of 14/09/2023 has passed; hence the issuing of a breach rather than remedial notice.

- 1.16 However, NHS Greater Manchester still requires the outstanding actions to be completed in order to be able to assess whether the Contractor is compliant with its Terms of Service.

- 1.17 For the avoidance of doubt, the outstanding actions are as follows:

1.17.1 Kamm Trading Ltd is to inform NHS Greater Manchester in writing of the name of its new Site Sponsor;

1.17.2 Kamm Trading Ltd is to provide evidence that the Data Security and Protection (DSP) Toolkit has been completed. The Data Security and Protection Toolkit is an online self-assessment tool that allows organisations to measure their performance against the National Data Guardian’s 10 data security standards. All organisations that have access to NHS patient data and systems must use this toolkit to provide assurance that they are practicing good data security and that personal information is handled correctly;

1.17.3 Mr Muhammad Harun Anwar, as the site’s Privacy Officer, is to conduct an internal review and provide an explanation as to why Smartcards have been used to undertake PDS retrievals during days and times not associated with routine pharmacy business; ascertain whether there is a gap in staff training to be addressed, and how this will be remedied if found to be the case. Once completed, Mr Anwar is to report his findings in writing to NHS Greater Manchester, confirm the steps taken to appropriately address this matter and lessons learned. Mr Anwar is also to provide written assurances that all pharmacy staff with Smartcard permissions will comply with the Terms and Conditions at all times in future (and as agreed during the Registration Authority team’s visit to the pharmacy site on 22/08/2023) and is to take

personal responsibility, as the site's Privacy Officer, for ensuring these conditions are met and maintained.

- 1.18 NHS Greater Manchester requires the information to be provided within 7 days of the date of this breach notice, and no later than 17:00 on 12/10/2023.
- 1.19 **You are required not to repeat the breach.**
- 1.20 Kamm Trading Ltd has a right of appeal to the Secretary of State against the issuing of this breach notice. 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 by email to nhsr.appeals@nhs.net or by post to Primary Care Appeals, NHS Resolution, 8th Floor, 10 South Colonnade, Canary Wharf, London, E14 4PU.
- 1.21 Please note that should you fail to comply with the requirements of this breach notice NHS Greater Manchester reserves the right to exercise its powers to take further action in relation to your inclusion in the pharmaceutical list in respect of the above-named premises. This may include removal of the premises from the pharmaceutical list under Regulation 73 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended."

2 The Appeal

In an email dated 3 November 2023 addressed to NHS Resolution, the Appellant appealed against the ICB's decision. The grounds of appeal are:

- 2.1 "I would like to appeal the breach of the notice for KAMM trading limited as the emails sent were not received. As soon as I was informed on email from [LC] regarding a different matter. I have actioned the email promptly. I have asked all correspondence to come to my NHS mail going forward."

3 Summary of Representations

The Commissioner

- 3.1 "Thank you for your letter dated 08/11/2023 advising of the above appeal, and for your agreement to extend the response period for receipt of NHS Greater Manchester's representations until today (22/12/2023). NHS Greater Manchester wishes the following observations to be taken into consideration.
- 3.2 Kamm Trading Ltd was issued with a breach notice on 05/10/2023 which is attached for reference.
- 3.3 NHS Resolution will note that Kamm Trading Ltd's appeal:
 - 3.3.1 does not challenge or dispute the content of the breach notice;
 - 3.3.2 does not indicate that it believes there was a failure to follow due process by NHS Greater Manchester; and
 - 3.3.3 does not indicate that it believes the action taken by NHS Greater Manchester was unjustified or disproportionate.
- 3.4 In fact, Kamm Trading Ltd provided NHS Greater Manchester with a full response to the breach notice actions (response received by email on 17/11/23), and NHS Greater Manchester's Pharmaceutical Services Regulations Committee (PSRC) – having reviewed Kamm Trading Ltd's response at its meeting on 30/11/23 – was satisfied that the identified breaches had been remedied and the matter could be closed. This outcome has been communicated to Kamm Trading Ltd.

- 3.5 The appeal is based on Kamm Trading Ltd apparently not receiving emails sent by NHS Greater Manchester. Kamm Trading Ltd did however respond to the initial email sent on 11/08/2023 to its NHS shared mailbox account, indicating that the mailbox was active/in use. Subsequent emails which reportedly were not received were sent by NHS Greater Manchester to the same mailbox. In any case, the above does not constitute grounds for appeal.
- 3.6 NHS Greater Manchester therefore respectfully requests that NHS Resolution (Primary Care Appeals) rejects the appeal and upholds NHS Greater Manchester's decision to issue a breach notice; for the reasons set out both in the breach notice and the above observations."

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, the NHSCB 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 I note that the pharmacy is included on the pharmaceutical list and that there is no dispute between the parties with regard to this.
- 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 The Breach Notice states:

"NHS Greater Manchester wrote to Kamm Trading Ltd ("the Contractor") on 11/08/2023 (copy attached) and received a brief response the same day (11/08/2023) which did not satisfactorily address the actions identified in NHS Greater Manchester's letter. The Contractor was informed by email on 14/08/2023 that the response received was insufficient, and that all actions identified in the letter still required completion by 25/08/2023 (i.e. 14 days from the date of NHS Greater Manchester's letter).

The Contractor failed to acknowledge or respond within the 14 day deadline.

NHS Greater Manchester wrote to the Contractor again on 07/09/2023 to remind the Contractor that although the Registration Authority Team had visited the pharmacy site on 22/08/2023 and completed the actions relating to Smartcard access/training, there were still a number of actions from the original letter of 11/08/2023 outstanding. The Contractor was advised that the matter had been discussed at the Pharmaceutical Services Regulations Committee (PSRC)'s meeting on 31/08/2023 and a final deadline extension had been agreed for the Contractor to provide the requested written confirmation/evidence to demonstrate that all identified actions had been completed.

The Contractor again failed to acknowledge or respond within the extended deadline i.e. by 14/09/2023."

- 5.7 I have been provided with a copy of the initial letter from the Commissioner to the Appellant dated 11 August 2023, although I have not been provided with a copy of the Appellant's response or the Commissioner's subsequent communications. I note the Appellant's comment that *"the emails sent were not received"*. However, in response, the Commissioner comments that the Appellant *"did however respond to the initial email sent on 11/08/23 to its NHS shared mailbox account, indicating that the mailbox was active/in use."* There is no dispute from the Appellant in this regard. I am therefore of the view that the Appellant had the opportunity to enter into local dispute resolution with the Commissioner but did not do so. There is no dispute raised by either party that the local dispute resolution process has not been exhausted. Given that both parties do not dispute that local dispute resolution has been exhausted I am content that I can deal with this matter.

- 5.8 The Appellant seeks to appeal against the decision of the Commissioner to issue the Breach Notice for its failure to provide the requested information in response to the Commissioner's letter dated 11 August 2023.

- 5.9 I note that the Breach Notice refers to Schedule 4, Part 4, Paragraph 35 of the Regulations which states:

35. Inspections and access to information

...

(3) P must, at the request of the NHSCB or of X, allow it or X access to any information which it or X reasonably requires—

(a) for the purposes mentioned in sub-paragraph (1); or

(b) in the case of the NHSCB, in connection with its functions that relate to pharmaceutical services.

- 5.10 I note that the Commissioner wrote to the Appellant on 11 August 2023 to inform it that an audit of Smartcard activity had been undertaken which identified the Appellant as *"an outlier requiring further investigation"*. The letter went on to detail the findings of the audit and to inform the Appellant that Smartcard permissions had been revoked until such time as it had satisfactorily completed a number of actions detailed in the letter. The Appellant was given 14 days until 25 August 2023 to provide a written response. The Commissioner states that the Appellant submitted a brief response the same day (11 August 2023) which did not satisfactorily address the actions identified in the letter. The Commissioner informed the Contractor by email dated 14 August 2023 that the response was insufficient and that the actions identified in the letter still required completion within the 14 days. I note that the Contractor failed to respond as requested.
- 5.11 The Commissioner states that it wrote to the Appellant again on 7 September 2023 to remind it that, although the actions relating to Smartcard access/training had been completed, there were still a number of actions from the letter dated 11 August 2023 that remained outstanding. The letter further indicated that the matter had been

discussed at a Pharmaceutical Services Regulations Committee (“PSRC”) meeting on 31 August 2023 and that a final deadline had been agreed by which the Appellant should provide the requested information to demonstrate that the various actions has been completed. I note that the Appellant again failed to respond and at a further meeting of the PSRC on 28 September 2023 it was agreed to issue the Breach Notice.

- 5.12 There is no dispute that the Appellant did not provide the information within the deadlines set by the Commissioner. Whilst I am mindful of the Appellant’s comment that it did not receive the emails sent, this is difficult to reconcile with the Commissioner’s undisputed comment that the Appellant did respond to its initial email dated 11 August 2023. There is no suggestion by the Appellant that there was a problem with the mailbox in question. The Commissioner states that the subsequent emails were sent to the same mailbox.
- 5.13 I therefore conclude that by failure to provide the information requested in the Commissioner’s letter dated 11 August 2023 by the deadlines given, the Appellant was in breach of paragraph 35(3), Schedule 4 of the Regulations.
- 5.14 I next consider whether the failure to provide the requested information is a breach which is capable of remedy. As noted in paragraph 5.3 above, the Regulations do not contain a definition as to what constitutes a breach of terms of service which is or is not capable of remedy. A common-sense interpretation is that a breach is unable to be rectified.
- 5.15 The Appellant was asked to submit the requested information within 14 days, which was subsequently extended. Submission of the information even if not within the given timescale would have remedied or rectified the breach. Further I note that there is no timescale set out in this provision of the Regulations by which to respond to a request for information. If there had been, the breach could not have been remedied.
- 5.16 Under Regulation 70 of the Regulations, a remedial notice may be issued:
- “70(1) Where an NHS chemist (C) breaches a term of service and the breach is capable of remedy, the NHSCB may by a notice (“a remedial notice”) require C to remedy the breach.”*
- 5.17 I consider that both remedial and breach notices carry the same weight in terms of severity of possible consequence, with the difference being that a remedial notice requires the remedy of the breach, and the breach notice requires an NHS chemist to not repeat the breach. As the Appellant failed to provide the information within the timescale set by the Commissioner, it was entirely appropriate to require the Appellant to remedy the breach.
- 5.18 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.
- 5.19 As a result of the comments I make above, I am of the view that:
- 5.19.1 the Appellant did not respond to the request for information within the timeframe set by the Commissioner; and
- 5.19.2 such action constitutes a breach of the Appellant’s terms of service by virtue of paragraph 35, which is capable of remedy.
- 5.20 Although I am substituting the Commissioner’s decision to issue the Breach Notice with a decision to issue a remedial notice, I note that the Commissioner has confirmed that the Appellant subsequently provided a full response to the actions identified in the Breach Notice by email dated 17 November 2023. I note further that the PSRC

reviewed the response at its meeting on 30 November 2023 and determined that the matter could be closed, therefore the breach has been remedied. There is therefore no action for the Appellant to take.

6 Decision

6.1 Pursuant to paragraph 9(5)(b) of Schedule 3 to the Regulations, I substitute the decision of the Commissioner to issue the Breach Notice with the decision to issue a remedial notice with the same wording except for the changes below:

- 6.1.1 substitute all references to “breach notice” and “regulation 71” with reference to “remedial notice” and “regulation 70”; and
- 6.1.2 substitute the requirement to not repeat the breach with the requirement to remedy the breach.

**Head of Appeals
NHS Resolution**