

1 April 2025

REF: SHA/26426

**APPEAL AGAINST BEDFORD, LUTON AND MILTON
KEYNES ICB DECISION REGARDING A BREACH
NOTICE AT HOT CHEMIST, 39 CARTERS LANE, KILN
FARM, MILTON KEYNES, BUCKINGHAM, MK11 3HL**

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:

Hot Chemist
Hertfordshire and West Essex ICB on behalf of Bedford, Luton and Milton Keynes ICB

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1 The Breach Notice

A Breach Notice dated 21 November 2024 was sent to Hot Chemist (FTW55) ("the Appellant") in respect of 39 Carters Lane, Kiln Farm, Milton Keynes, Buckingham, MK11 3HL.

1.1 "I am writing to inform you that the ICB Pharmaceutical Services Regulatory Committee (PSRC) met on Wednesday 16th October 2024, where it was made aware of the failure of Hot Chemist (FTW55) to submit the annual self-assessment of the Data Security and Protection Toolkit for 2023/2024 by the deadline of 30th June 2024.

1.2 The decision was made by the PSRC, in line with your Terms of Service, Schedule 4, Part 4, Other Services para 28 (2) (f), that the attached Breach Notice be served."

Breach Notice

1.3 "Name of contractor: Hot Pharma Ltd T/A Hot Chemist (FTW55).

1.4 Address of premises: 39 Carters Lane, Kiln Farm, Milton Keynes, Buckingham, MK11 3HL.

1.5 Date of inclusion in the pharmaceutical list for the area of Milton Keynes Health & Wellbeing Board: 22 July 2016.

1.6 This is a breach notice issued under Regulation 71 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, and the Approved particulars – Information Governance Programme published by NHS England on 19 July 2023.

1.7 Breaches of terms of service: breach notices

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.

1.8 Accordingly, you are required to ensure that you do not repeat the breach detailed in this notice. Failure to do so may lead the NHSCB to remove the above-named premises from its Pharmaceutical List. Regulation 73 (1) (b) states:

73.—(1) The NHSCB may remove an NHS chemist (C) from a pharmaceutical list, or remove the listing of a particular listed chemist premises in relation to C, if C

(b) has breached C's terms of service, and

- (i) *C has repeatedly been issued with remedial notices or breach notices (or both) in relation to the relevant term of service,*
- (ii) *previously been issued with a remedial notice or breach notice in relation to the relevant term of service, and the NHSCB is satisfied that C is likely to persist in breaching the term of service without good cause,*
- (iii) *C has repeatedly been issued with remedial notices or breach notices (or both) in relation to different terms of service, and the NHSCB is satisfied that C is likely to persist in breaching C's terms of service without good cause.*

1.9 Nature of the breach:

1.10 Failure to submit the annual self-assessment of the Data Security and Protection Toolkit for 2023/2024 in line with paragraph 28(2)(f)(ii), Schedule 4 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended which states:

1.11 Clinical governance and the promotion of healthy living

28.—(1) *An NHS pharmacist (P) must, in connection with the pharmaceutical services provided by P, participate, in the manner reasonably required by the NHSCB, in an acceptable system of clinical governance and for the promotion of healthy living.*

(2) *For these purposes a system of clinical governance and for the promotion of healthy living is “acceptable” if it is considered acceptable by the NHSCB and comprises the following components—*

(f) an information governance programme, which provides for—

- (i) compliance with approved procedures for information management and security, and*
- (ii) submission of an annual self-assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the NHSCB to access that assessment*

1.12 Failure to submit the annual self-assessment of the Data Security and Protection Toolkit for 2023/2024 in line with Approved particulars – Information Governance Programme published by NHS England on 19 July 2023 which states:

- *Community pharmacies must have completed and submitted the Data Security and Protection Toolkit assessment by 30 June each year.*

1.13 You are required not to repeat this breach of failure to submit the annual self-assessment of the Data Security and Protection Toolkit in line with paragraph 28(2)(f)(ii), Schedule 4 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and the “approved particulars – Information Governance Programme” published by NHS England on 19 July 2023.

1.14 E-mail used for to send reminders of the DSP Toolkit deadline: pharmacy.ftw55@nhs.net

Appeals:

- 1.15 You have a right of appeal to the Secretary of State against the issuing of this breach notice.
- 1.16 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: NHS Resolution, 8th Floor, 10 South Colonnade, Canary Wharf, London, E14 4PU.
- 1.17 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 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.
- 1.18 Date: 21 November 2024.”

2 The Appeal

In a letter dated 10 December 2024 addressed to NHS Resolution, the Appellant appealed against Bedford, Luton and Milton Keynes ICB (“the Commissioner”) decision. The grounds of appeal are:

- 2.1 “We acknowledge receipt of your correspondence regarding the breach notice issued under Schedule 4, Part 4, paragraph 28(2)(f)(ii) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, which requires the submission of the annual Data Security and Protection (DSP) Toolkit to demonstrate compliance with approved data management and security procedures.
- 2.2 While we fully acknowledge this breach, we would like to provide a detailed explanation of the circumstances, supported by evidence, and highlight the corrective measures we have implemented to prevent recurrence.
- 2.3 **June 2024 – First-Time Submission Attempt:** On 27th June 2024, our Superintendent Pharmacist, new to the DSP Toolkit submission process, emailed [CK] seeking guidance on how to complete the submission. (see Evidence 1: Screenshot of email correspondence)
- 2.4 **Response from NHS:** Later the same day, [CK] replied, redirecting us to the DSP Toolkit help page for further guidance. However, no specific instructions were provided regarding the exact submission process; (see Evidence 2: Screenshot of reply email)
- 2.5 **Attempted Submission:** On 27th June 2024, the Superintendent Pharmacist emailed a completed PDF version of the DSP Toolkit to the Exeter Helpdesk (exeter.helpdesk@nhs.net), providing all required business details. No response was received confirming or rejecting the submission. (see Evidence 3: Screenshot of submission email)
- 2.6 **Follow-Up with NHS Digital:** On 1st July 2024, we contacted NHS Digital referencing case number CS0723419 to confirm whether our submission had been accepted. Despite follow-ups, it was only discovered on 24th July 2024 that the organisation administrator details in the NHS system had not been updated following our ownership transition in December 2023, further complicating the Process.

(see Evidence 4: Screenshot of follow-up email)

- 2.7 **Final Efforts:** On 9th July 2024, another email was sent to NHS Digital requesting confirmation of acceptance for the submitted toolkit. Unfortunately, this was after the 30th June 2024 deadline.
(see Evidence 5: Screenshot of follow-up email)
- 2.8 Following an internal analysis, we identified two primary factors contributing to the breach:
- 2.9 **Handover Transition** During the ownership change in December 2023, the outgoing Superintendent Pharmacist provided handover instructions, which included the DSP Toolkit submission. The incoming superintendent followed these instructions but was unaware of the exact submission process required under Schedule 4, Part 4, Paragraph 28(2)(f)(ii) of the NHS Regulations.
- 2.10 **Submission Process Confusion** Despite our efforts, we misunderstood the requirement that the DSP Toolkit must be submitted through the approved online system, and incorrectly assumed that emailing the completed PDF fulfilled our obligation.
- 2.11 **Corrective Actions Take** To address the breach and ensure future compliance, we have implemented the following measures.
- 2.12 **Submission of the DSP Toolkit** We have now submitted the, DSP Toolkit on line as per the requirements, with the hope of achieving full compliance as of 10th December 2024.
(See attached Certificate)
- 2.13 **Improved Documentation**, All NHS submission deadlines, including the DSP Toolkit, have been formally documented, and periodic calendar alerts have been set to ensure timely compliance.
- 2.14 **Centralised Communication** All NHS-related correspondence is now directed to a single monitored email address to avoid miscommunication or missed guidance.
- 2.15 **Leadership Awareness and Training** We have conducted training sessions with the Director, Superintendent Pharmacist, and Business Manager to ensure complete understanding of all mandatory obligations under the NHS contract.
- 2.16 **Periodic Compliance Audits** We will conduct quarterly reviews of all regulatory obligations to ensure compliance across all areas.
- 2.17 **Request for Consideration** While we are aware of our right to appeal under Regulation 71 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, we are not appealing this breach notice, as we accept that our submission did not meet the legal requirements.
- 2.18 However, we respectfully request that the mitigating factors, including:
- 2.19 Our genuine attempts to comply, the absence of rejection feedback from NHS Digital, and the corrective actions we have implemented be taken into account.
- 2.20 Given that the DSP Toolkit has now been submitted and compliance achieved, we kindly ask for the breach notice to be removed on this occasion.

- 2.21 We remain committed to upholding the highest standards of compliance and ensuring that such issues are avoided in the future.”

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 1 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 Regulation Committee (PSRC) which is also hosted by HWE ICB.
- 3.1.2 Thank you for your letter dated 02 January 2025 advising us that Hot Pharma Ltd T/A Hot Chemist (the Appellant) have submitted an appeal against the decision by Bedford, Luton, Milton Keynes ICB to issue a breach notice for failing to complete the annual Data Security and Protection Toolkit (DSP Toolkit) by 30 June 2024. Having reviewed the letter of appeal from 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 they did not complete the DSP Toolkit by the 30 June. This is detailed on page one of the letter of appeal: “*we fully acknowledge this breach.*” 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.
- 3.1.4 We wish to make the following representations.
- 3.1.5 It is a regulatory requirement under the terms of service, that all pharmacies complete the DSP Toolkit each year - paragraph 24(2)(f)(ii), Schedule 4 of the Regulations.
- 3.1.6 The Approved Particulars – Information Governance Programme published by NHS England on 19 July 2023 also need to be considered in view of the specific timescales. The Approved Particulars state:
- 3.1.7 Community pharmacies must have completed and submitted the Data Security and Protection Toolkit assessment by 30 June each year.
- 3.1.8 Enclosed with this letter are the following documents:
- 3.1.8.1 Committee Report presented at PSRC seeking permission to issue a breach notice. (Information has been anonymised where referencing “other” contractors).
- 3.1.8.2 An extract of the minutes from the PSRC.
- 3.1.8.3 The letter that was issued to the Appellant as part of dispute resolution.
- 3.1.8.4 A copy of NHS England Approved particulars – Information Governance Programme

- 3.1.9 NHS Resolution will note from the Committee Report, the multiple reminders and opportunities contractors had to complete the DSP Toolkit by the required deadline. The reminders are sent to assist contractors however contractors should be aware of the requirements of the Regulations and Approved Particulars and have a duty to ensure they comply with all their obligations.
- 3.1.10 Following the deadline of 30 June, the ICB was provided with a list of contractors who had failed to make a submission. The list is provided by the NHS Business Services Authority who support all ICBs nationwide with this process. The Appellant was detailed as a contractor who had failed to complete the DSP Toolkit.
- 3.1.11 Prior to any contractual action being taken, the ICB undertook dispute resolution. A letter dated 24 July 2023 (it is noted this was a typo on the letter and should read 24 July 2024) was sent to the Appellant noting that our records indicated the DSP Toolkit had not been submitted. The Appellant was asked to confirm if this was correct and if so, provide an explanation as to why the submission was not made. If our records were incorrect, the Appellant was asked to provide information to demonstrate compliance.
- 3.1.12 The letter was sent via email to the Appellant's generic shared nhs.net email address as detailed on the pharmaceutical list (pharmacy.ftw55@nhs.net) and also their second nominated email address help@hotchemist.co.uk. NHS Resolution will be aware of the contractual requirement to ensure these mailboxes are checked regularly. Delivery receipts were received.
- 3.1.13 The Appellant did not respond to the letter and therefore the PSRC decided, based on the information available at the time, namely that the Appellant had not made a submission, and despite attempting via dispute resolution to engage with the Appellant, no response was received, to issue the breach notice.
- 3.1.14 The ICB notes that on receipt of the breach notice, the Appellant responded by letter which was received on the 14 December 2024. A response was being prepared by the ICB, however, it crossed over with communication from NHS Resolution advising us that the Appellant had lodged an appeal. The ICB felt it would be more efficient to respond with representations to the appeal.
- 3.1.15 In reference to the letter submitted it is noted that the Appellant acknowledges they were confused about the process and did not make a correct submission within the timeframe. The ICB recognises that the Appellant has undertaken some reflective practise, identified "*where things went wrong*" and has put steps in place to ensure the requirements of the DSP Toolkit are met in future years. This is positive however cannot negate the need to ensure that the Regulations are met. There has been a breach of paragraph 24(2)(f)(ii), Schedule 4 of the Regulations and this cannot be remedied. The breach notice should stand."

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 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:

“Nature of the breach:

Failure to submit the annual self-assessment of the Data Security and Protection Toolkit for 2023/2024 in line with paragraph 28(2)(f)(ii), Schedule 4 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended which states:

Clinical governance and the promotion of healthy living

- 28.—(1) *An NHS pharmacist (P) must, in connection with the pharmaceutical services provided by P, participate, in the manner reasonably required by the NHSCB, in an acceptable system of clinical governance and for the promotion of healthy living.*
- (2) *For these purposes a system of clinical governance and for the promotion of healthy living is “acceptable” if it is considered acceptable by the NHSCB and comprises the following components—*
- (f) *an information governance programme, which provides for—*
- (i) *compliance with approved procedures for information management and security, and*

- (ii) *submission of an annual self-assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the NHSCB to access that assessment*

Failure to submit the annual self-assessment of the Data Security and Protection Toolkit for 2023/2024 in line with Approved particulars – Information Governance Programme published by NHS England on 19 July 2023 which states:

- *Community pharmacies must have completed and submitted the Data Security and Protection Toolkit assessment by 30 June each year.*

You are required not to repeat this breach of failure to submit the annual self-assessment of the Data Security and Protection Toolkit in line with paragraph 28(2)(f)(ii), Schedule 4 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and the “approved particulars – Information Governance Programme” published by NHS England on 19 July 2023.

E-mail used for to send reminders of the DSP Toolkit deadline: pharmacy.ftw55@nhs.net.”

- 5.7 I note the Commissioner’s comments that after the deadline of 30 June 2024, it had been provided with a list of contractors who had failed to make a submission, and that the Appellant was included on this list. The Commissioner states that it sent a letter to the Appellant via its email address pharmacy.ftw55@nhs.net and also to the Appellant’s second nominated address help@hotchemist.co.uk and the Commissioner provided a copy of that letter within its representations. The Commissioner notes that delivery receipts were received but no response was received from the Appellant and therefore a decision was made to issue the Breach Notice.
- 5.8 The Appellant has not responded to explain why it did not respond to the Commissioner’s letter of 23 July 2024 enquiring why its DSP Toolkit had not been submitted. It is unfortunate that it did not do so at the time as this was a missed opportunity to resolve the matter prior to the Commissioner proceeding to issue the Breach Notice.
- 5.9 I note that there are contradictory statements within the letter from the Appellant of 10 December 2024. It is unclear if the Appellant is seeking to appeal against the Commissioner’s decision to issue the Breach Notice. In this regard, the Appellant states:
- “While we fully acknowledge this breach, we would like to provide a detailed explanation of the circumstances, supported by evidence, and highlight the corrective measures we have implemented to prevent recurrence.”*
- 5.10 The Appellant goes on to state:
- “Request for Consideration*** *While we are aware of our right to appeal under Regulation 71 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, we are not appealing this breach notice, as we accept that our submission did not meet the legal requirements.”*
- 5.11 However, the Appellant concludes the letter of 10 December 2024 by stating:
- “Given that the DSP Toolkit has now been submitted and compliance achieved, we kindly ask for the breach notice to be removed on this occasion.”*

- 5.12 The Commissioner, in its representations, is of the view that, given the Appellant has confirmed that they did not submit the DSP Toolkit within the relevant period and that it is stated in the appeal *“we are not appealing this breach notice, as we accept that our submission did not meet the legal requirements”* that the Breach Notice as issued should stand.
- 5.13 The Appellant has not responded to the Commissioner’s comments in their representations regarding its view that the Breach Notice should stand but the Appellant does set-out some mitigating factors to the breach in the appeal letter which includes being new to the process and a lack of guidance and support. To my mind these are not exceptional and whilst I acknowledge the Appellant emailed the submission, this was not in the required form.
- 5.14 I also commend the actions that the Appellant has taken and the *“corrective measures”* that have since been implemented to avoid a repetition of this situation. I further note the statement in the appeal that *“we have now submitted the DSP Toolkit as per the requirements, with the hope of achieving full compliance as of 10 December 2024”* however, I have not been provided with any evidence of this submission and the Commissioner also remains silent on this point.
- 5.15 I am of the view that I have not been provided with sufficient evidence to show that the Appellant submitted the DSP Toolkit in line with the Regulations, by the required deadline.

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