

28 September 2023

REF: SHA/26059

**APPEAL AGAINST NHS GREATER MANCHESTER
INTEGRATED CARE DECISION REGARDING A
BREACH NOTICE AT WELLBROOK VENTURES LTD
(FQR19) AND (FFA91) AT 150 DEANE ROAD, BOLTON,
BL3 5DL AND 226 DEANE ROAD, BOLTON, BL3 5DP**

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)(a) of Schedule 3 to the Regulations I confirm the decision of NHS Greater Manchester to issue the breach notice.

A copy of this decision is being sent to:

Wellbrook Ventures Ltd (the Appellant)
NHS Greater Manchester Integrated Care

Advise / Resolve / Learn

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1 The Breach Notice

A Breach Notice dated 12 July 2023 was sent to Wellbrook Ventures Ltd ("the Appellant") in respect of premises at 150 Deane Road, Bolton, BL3 5DL (FQR19) and 226 Deane Road, Bolton, BL3 5DP (FFA91).

1.1 "Name of contractor:

1.1.1 Wellbrook Ventures Ltd

1.2 Address of premises:

1.2.1 150 Deane Road, Bolton, BL3 5DL (FQR19)

1.2.2 226 Deane Road, Bolton, BL3 5DP (FFA91)

1.3 Date of inclusion in the pharmaceutical list for the area of Bolton Health and Wellbeing Board (HWB): 02/08/2010 (FQR19), 01/12/2011 (FFA91)

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 It has come to NHS Greater Manchester's attention that a director of Wellbrook Ventures Ltd, Imraan Khan, failed to declare that they had become the subject of a GPhC investigation at the time they were first made aware by the GPhC. Furthermore, Imraan Khan is yet to formally declare this matter to NHS Greater Manchester despite a Community Framework Assurance Framework (CPAF) visit which took place on 14/06/2023, during which Imraan Khan confirmed they were aware of the GPhC investigation and was reminded by attending NHS Greater Manchester officers of the requirement to formally declare the matter in order to comply with the ongoing Terms of Service obligations relating to Fitness to Practise.

1.8 Schedule 4, Part 4, Paragraph 31 of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations) states:

"Duty to provide information about fitness matters as they arise"

31.-(1) Subject to paragraph 33, an NHS pharmacist (P) and, where P is a body corporate, every director and superintendent of P must, within 7 days of its occurrence, inform the Primary Care Trust in writing if they-

- (a) are convicted of any criminal offence in the United Kingdom;*
- (b) are bound over following a criminal conviction in the United Kingdom;*
- (c) accept a police caution in the United Kingdom;*
- (d) have, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging them absolutely (without proceeding to conviction);*
- (e) have accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995(14) (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992(15) (penalty as alternative to prosecution);*
- (f) have been convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England, could lead to a criminal conviction in England;*
- (g) are charged in the United Kingdom with a criminal offence, or are charged elsewhere than in the United Kingdom with an offence where the originating events, if they took place in England, could lead to a criminal conviction in England;*
- (h) are notified by any licensing, regulatory or other body of the outcome of any investigation into their professional conduct, and there is a finding against them;*
- (i) become the subject of any investigation into their professional conduct by any licensing, regulatory or other body;*
- (j) become the subject of any investigation into their professional conduct in respect of any current or previous employment, or are notified of the outcome of any such investigation and any finding against them;*
- (k) become the subject of any investigation by the NHS BSA in relation to fraud;*
- (l) become the subject of any investigation by another primary care organisation which might lead to their removal from a relevant list; or*
- (m) are removed, contingently removed or suspended from, refused inclusion in or conditionally included in any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision,*

and must give details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome."

1.9 (Please note that references to the Primary Care Trust in the above Paragraph is replaced with the current commissioning body, NHS Greater Manchester).

1.10 It is considered that Wellbrook Ventures Ltd is presently in breach of Schedule 4, Part 4, Paragraph 31 (1)(i) as Imraan Khan did not formally declare the GPhC investigation

to NHS Greater Manchester within 7 days of become [sic] aware of it; and is still to make a declaration in this respect despite being reminded of the requirement to do so during the CPAF visit of 14/06/2023.

- 1.11 The requirement to notify within 7 days cannot now be remedied due to the length of time which has now passed since director Imraan Khan became aware of the GPhC's investigation. Imraan Khan is however still required to formally notify NHS Greater Manchester of the GPhC investigation, and the notification must be in writing by email to england.gmtop@nhs.net and must include details of the investigation and any proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.
- 1.12 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 (insert date) [sic].
- 1.13 You are required not to repeat the breach.
- 1.14 Wellbrook Ventures 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.
- 1.15 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 19 July 2023 and addressed to NHS Resolution, Wellbrook Ventures Ltd (the Appellant) appealed against NHS Greater Manchester's decision. The grounds of appeal are:

- 2.1 "I hope this message finds you well. I am writing to appeal the breach notice issued to me on 12th July 2023 by NHS Greater Manchester. The notice pertains to my failure to declare that I had become the subject of a GPhC investigation. I believe there might have been a misunderstanding or oversight in this matter.
- 2.2 I want to emphasize my sincere commitment to adhering to all rules, regulations, and obligations set forth by the regulating authority. However, I respectfully request your attention to the following points as I seek a reconsideration of the breach notice:
- 2.3 **Clarification of the alleged Breach and mitigating circumstances:** As a registered pharmacy technician with GPhC and a director of the mentioned company, I was subject to a GPhC investigation which is still ongoing; I became aware of this around mid-2021. Upon receiving the initial letter from GPhC, I promptly informed my Superintendent Pharmacist at the time, believing that the company's superintendent, who was already aware of the complaint from the outset, had made the necessary report. However, during the Contract Assurance visit on 16th May 2023 from NHS Greater Manchester team, I discovered that this had not been done. I also mistakenly assumed that informing NHS Greater Manchester officers during this visit about the investigation would suffice, considering their association with NHS England.

Nonetheless, I now understand the correct procedure and take full responsibility for the oversight.

- 2.4 I sincerely apologize for any confusion or inconvenience caused by this oversight. My commitment to compliance is unwavering, and I assure you that I will take all necessary steps to ensure strict adherence to reporting requirements in the future.
- 2.5 **Corrective Measures:** Upon receiving the breach notice, I have taken immediate action to rectify the situation and prevent any further non-compliance. I have informed NHS Greater Manchester in writing about the incident on 19th July 2023, which will ensure full compliance moving forward.
- 2.6 **Previous Compliance Record:** It is essential to note that prior to this incident, I have maintained a commendable record of compliance. I have consistently strived to meet all requirements and standards, and this isolated event does not reflect my usual approach to adhering to regulations.
- 2.7 **Appeal for Leniency:** I respectfully request that you consider my appeal with leniency and understanding. I assure you of my utmost commitment to rectifying any mistakes and ensuring full compliance in the future.
- 2.8 In light of the points mentioned above, I kindly request a review of the breach notice and a reconsideration of any punitive actions. I believe that an equitable and fair resolution can be reached, one that ensures accountability and compliance while recognizing the extenuating circumstances surrounding this incident.
- 2.9 I am more than willing to provide any additional information or documentation that may assist in this appeal process.
- 2.10 Please let me know if there is a specific procedure or documentation you require from me.
- 2.11 Thank you for your attention to this matter. I eagerly await a favourable response, and I remain committed to working collaboratively with your office to address and resolve this issue appropriately.”

3 Summary of Representations

This is a summary of representations received on the appeal. A summary of those representations made to NHS England are only included insofar as they are relevant and add to those received on the appeal.

- 3.1 NHS Greater Manchester Integrated Care
 - 3.1.1 “NHS Greater Manchester’s Pharmaceutical Services Regulations Committee (PSRC) has reviewed the content of the appeal and wishes to make the following observations.
 - 3.1.2 Wellbrook Ventures Ltd has provided a copy of NHS Greater Manchester’s breach notice as part of its appeal. Primary Care Appeals will note that the breach notice was issued for failure to comply with the Terms of Service relating to the requirement to notify the commissioner (NHS Greater Manchester) within seven days of becoming aware of an investigation by a licensing body - in this case, the General Pharmaceutical Council (GPhC).
 - 3.1.3 In the appeal, Mr Imraan Khan (Director of Wellbrook Ventures Ltd) has admitted there was a failure to formally notify NHS Greater Manchester within seven days of becoming aware that he was subject to a GPhC investigation. The reasons stated in the appeal do not provide mitigation for failing to comply

with the Terms of Service regarding a pharmacy contractor's duty to provide information about fitness matters as they arise. The NHS Greater Manchester officers in attendance at the CPAF visit (referred to by Mr Khan in the appeal) report that a comprehensive discussion took place with Mr Khan at the visit; during which the importance of formally notifying NHS Greater Manchester of the GPhC investigation was emphasised, and the process for doing so was clearly communicated.

3.1.4 Furthermore, Wellbrook Ventures Ltd has not indicated in its appeal that it believes there was a failure to follow due process by NHS Greater Manchester, nor that the action taken by NHS Greater Manchester was unjustified or disproportionate. In fact, the appeal confirms that there was a failure to meet the Terms of Service requirements for which the breach notice was ultimately issued. It is therefore unclear on what basis Wellbrook Ventures Ltd is appealing the issuing of the breach notice.

3.1.5 We therefore respectfully request that 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 I note that the breach notice states that NHS Greater Manchester Integrated Care ("NHS Greater Manchester") manages NHS community pharmacy contracts under delegation from NHS England since 1 July 2022. NHS Greater Manchester Integrated Care made the decision which is the subject of this appeal. NHS Resolution will issue this decision to NHS Greater Manchester.

5.2 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.

5.3 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;"

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

5.5 I note that the pharmacy is included on the pharmaceutical list and that there is no dispute between the parties with regard to this.

5.6 I note that the Breach Notice was issued pursuant to Regulation 71(1) and is a valid 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).

5.7 I note that Paragraph 31(1) of Schedule 4 states:

"Duty to provide information about fitness matters as they arise

31.-(1) Subject to paragraph 33, an NHS pharmacist (P) and, where P is a body corporate, every director and superintendent of P must, within 7 days of its occurrence, inform the Primary Care Trust in writing if they-

...

(i) become the subject of any investigation into their professional conduct by any licensing, regulatory or other body;

...

and must give details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome."

- 5.8 I note that the Breach Notice states that the Appellant had failed to declare to NHS England that Mr Imraan Khan, a director of Wellbrook Ventures Ltd, had become the subject of a GPhC investigation, within 7 days of being made aware of the investigation.
- 5.9 I note that the Appellant states that they first became aware of the GPhC investigation "around mid-2021". At this time they informed the Superintendent Pharmacist and believed that they would in turn inform NHS England. The Appellant discovered this had not been done during a CPAF visit by NHS Greater Manchester on 16 May 2023. The Appellant further states that they had mistakenly assumed that informing the officers of the GPhC investigation during this visit would suffice as notification.
- 5.10 I note that the Appellant states that upon receiving the Breach Notice they have taken immediate action to rectify the situation and informed NHS Greater Manchester of the GPhC investigation in writing on 19 July 2023.
- 5.11 I note NHS Greater Manchester's comments that during the CPAF visit on 16 May 2023, "a comprehensive discussion took place with Mr Khan at the visit; during which the importance of formally notifying NHS Greater Manchester of the GPhC investigation was emphasised, and the process for doing so was clearly communicated". I note that no response to this comment was received from the Appellant. I am mindful that even if the Appellant had notified NHS Greater Manchester immediately following the CPAF visit, the notification would still not have been provided within the timescale set out in the Regulations i.e. 7 days.
- 5.12 I have considered whether a breach of Paragraph 31(1) is capable of remedy. If the requirement were simply to notify the Commissioner, then it could be capable of remedy by provision of that notification. But the requirement in Paragraph 31(1) goes beyond that and requires the information to be provided within a specific timescale i.e. within 7 days. As the relevant timescale has now passed, while the notification can still be provided (and according to the Appellant it has), it is not possible to remedy the failure to provide the notification within the timescale.
- 5.13 Although the Appellant has referred to this as a "misunderstanding or oversight", I consider that the Regulations clearly envisaged proactive notification of the GPhC investigation by the Appellant within a set timescale and, in this case, this requirement was not adhered to. Regardless of the fact that the Appellant has now submitted a notification, I consider that it was within the discretion of NHS Greater Manchester as provided for in the Regulations to determine whether a notice should be issued in respect of the breach.

5.14 As a result of the comments I make above, I am of the view that:

5.14.1 the Appellant failed to notify NHS England within 7 days that they had become the subject of an investigation by the GPhC;

5.14.2 such action constitutes a breach of the Appellant's terms of service as set out in paragraph 31(1) of Schedule 4 to the Regulations;

5.14.3 NHS Greater Manchester was entitled to issue the Breach Notice.

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 NHS England or substitute for that decision any decision that NHS England 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 NHS Greater Manchester to issue the Breach Notice.

Head of Appeals
NHS Resolution