PUBLIC RECORD

**Dates**: 21/06/2023 - 29/06/2023

**Medical Practitioner's name:** Dr Timothy BAXTER

**GMC reference number:** 3166004

**Primary medical qualification:** MB BS 1986 University of London

**Type of case**
New – Misconduct and Conviction

**Outcome on facts**
Facts relevant to impairment found proved

**Outcome on impairment**
Not Impaired

**Summary of outcome**
Warning

**Tribunal:**

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| Legally Qualified Chair | Ms Morag Rea |
| Lay Tribunal Member: | Mr John Elliott |
| Medical Tribunal Member: | Dr Kamran Shahid |

| | |
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| Tribunal Clerk: | Mr Joel Taylor |

**Attendance and Representation:**

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| Medical Practitioner: | Present and represented |
| Medical Practitioner's Representative: | Mr Mark Shaw, KC, instructed by Wiley Law |
| GMC Representative: | Ms Sharon Beattie, KC |

**Attendance of Press / Public**

In accordance with Rule 41 of the General Medical Council (Fitness to Practise) Rules 2004 the hearing was held in public.

## Overarching Objective

Throughout the decision-making process the tribunal has borne in mind the statutory overarching objective as set out in s1 Medical Act 1983 (the 1983 Act) to protect, promote and maintain the health, safety and well-being of the public, to promote and maintain public confidence in the medical profession, and to promote and maintain proper professional standards and conduct for members of that profession.

## Determination on Facts - 27/06/2023

## Background

1. Dr Baxter qualified in 1986 from the University of London and, prior to the events which are the subject of the hearing, he had spent three years training in anaesthesia before moving into pharmaceutical medicine in 1989. At the time of the events Dr Baxter was the Global Medical Director for Reckitt Benckiser Pharmaceuticals ('RBP'), based in the United States, where he moved in 2006. RBP was subsequently demerged and Dr Baxter became the Chief Medical Director for Indivior. Whilst Dr Baxter holds a license to practise in the UK, he has never done so in the US and has not practised clinically for many years.

2. The allegation that has led to Dr Baxter's hearing can be summarised as follows; on 17 December 2020, Dr Baxter pleaded guilty and was subsequently sentenced for the misdemeanour crime of causing the introduction or delivery for introduction into interstate commerce of a drug that is misbranded, contrary to Title 21 of the United States Code, Sections 331(a) and 333(a)(1).

3. Dr Baxter's sentence included a fine of $100,000 and one year probation. The initial concerns were raised with the GMC on 11 January 2021 by Dr Baxter's self-referral. It is alleged that Dr Baxter did not alert the GMC to the fact that he had formally admitted the above criminal offence without delay.

4. Indivior had previously pleaded guilty to knowingly and wilfully making materially false statements to MassHealth in connection with the delivery of and payment for healthcare benefits in violation of Title 18, United States Code, section 1035. The company was ordered to forfeit $289,000,000, which is the sum, in aggregate, obtained directly or indirectly, as a result of the said offence.

5. The brief facts are: In October 2012, a Medical Affairs Manager ('MAM') at Indivior, who reported to Dr Baxter, submitted faulty data that exaggerated the difference between the paediatric consumption rates of Suboxone Film and Suboxone Tablets to MassHealth, the state Medicaid provider in Massachusetts. The information had been provided by RADARS; a research organisation instructed with the approval of Dr Baxter. The MAM later compounded that error by sharing a chart which, although peer reviewed and accurate in itself, added to the impression of exaggeration.

6. It is further alleged that the crime outlined above would constitute a crime if committed in England and Wales, namely being pursuant to the Business Protection from Misleading Marketing Regulations 2008; [Regulation 2, 2(1), 3, 6, 8(1) and 8(2)]; and/or alternatively, pursuant to the Human Medicines Regulations 2012 [Regulation 96, 338(1) and Part 13].

## The Outcome of Applications Made during the Facts Stage

7. The Tribunal proposed to amend the Allegation, under Rule 17(2)(c) of the General Medical Council (Fitness to Practise) Rules 2004, as amended ('the Rules'), to particularise the fourth paragraph of the Allegation but accepted the submission made by Ms Beattie, KC, on behalf of the GMC, that the paragraph should remain 'floating'. The Tribunal accepted the submission, made on behalf of Dr Baxter by Mr Shaw, KC, that the words *'inter alia'* should be added to paragraph 2 of the Allegation.

8. The Tribunal determined to grant, in part, an application made by Ms Beattie, under Rule 34(1) to admit further evidence. The details of this determination can be found in Annex A.

9. The Tribunal made a determination on the approach it should take when considering the fourth paragraph of the Allegation. It determined that it should take a narrow, equivalency approach the details of which are set out in Annex B.

10. The Tribunal refused an application made by Mr Shaw under Rule 17(2)(g) that there was no case for Dr Baxter to answer with regards to paragraph 3 of the Allegation. The details of this decision are set out in Annex C.

## The Allegation and the Doctor's Response

11. The Allegation made against Dr Baxter is as follows:

That being registered under the Medical Act 1983 (as amended):

1. On 17 December 2020, at the United States District Court Western District of Virginia, you were convicted of causing the introduction or delivery for introduction into interstate commerce of a drug that is misbranded, contrary to Title 21 of the United States Code, Sections 331(a) and 333(a)(1). Admitted and found proved

2. On 17 December 2020, at the United States District Court Western District of Virginia, you were sentenced inter alia to: Amended under Rule 17(2)(c)

    a. pay a fine of $100,000.00; Admitted and found proved

    b. one year probation. Admitted and found proved

3. You failed to notify the General Medical Council without delay that you had formally admitted to the criminal offence outlined at paragraph 1. To be determined

The offence outlined at a paragraph 1, if committed in England and Wales, would constitute a criminal offence (see Annex A). To be determined

And that by reason of the matters set out above your fitness to practise is impaired because of your:

a. conviction in relation to paragraphs 1 and 2; To be determined

b. misconduct in relation to paragraph 3. To be determined

12. For the sake of clarity, where 'Annex A' appears in the Allegation, this determination will use 'Schedule 1'.

## The Admitted Facts

13. At the outset of these proceedings, through his counsel, Mr Shaw, KC, Dr Baxter made admissions to some paragraphs and sub-paragraphs of the Allegation, as set out above, in accordance with Rule 17(2)(d). In accordance with Rule 17(2)(e), the Tribunal announced these paragraphs and sub-paragraphs of the Allegation as admitted and found proved.

## The Facts to be Determined

14. In light of Dr Baxter's response to the Allegation made against him, the Tribunal is required to determine whether Dr Baxter failed to notify the GMC without delay that he had formally admitted to a criminal offence and also whether Dr Baxter's conviction in the US would constitute an offence if committed in England and Wales (the fourth paragraph).

## Witness Evidence

15. Dr Baxter provided his own witness statement dated 18 August 2022.

16. The Tribunal also received evidence on behalf of Dr Baxter in the form of witness statements from the following witnesses who were not called to give oral evidence:

- Dr A, Dr Baxter's responsible officer.

## Documentary Evidence

17. The Tribunal had regard to the documentary evidence provided by the parties. This evidence included but was not limited to The Information, which formed the case against Dr Baxter, Dr Baxter's written Plea Agreement and Record of Conviction and Information for Indivior.

## The Tribunal's Approach

18. In reaching its decision on facts, the Tribunal has borne in mind that the burden of proof rests on the GMC and it is for the GMC to prove the Allegation. Dr Baxter does not need to prove anything. The standard of proof is that applicable to civil proceedings, namely the balance of probabilities, i.e., whether it is more likely than not that the events occurred.

19. The LQC reminded the Tribunal of Rule 34(3):

> *'Production of a certificate purporting to be under the hand of a competent officer of a Court in the United Kingdom or overseas that a person has been convicted of a criminal offence or, in Scotland, an extract conviction, shall be conclusive evidence of the offence committed.'*

20. The LQC advised the Tribunal that it is entitled to consider what has been adjudicated upon in the overseas case without reference to experts, and to make an independent finding about the overseas offence. The LQC referred to the case of *Schulze Allen v Royal College of Veterinary Surgeons [2019] UKPC 34* which establishes this principle.

21. The LQC amended their proposed legal advice in respect of *Barnett v GMC 2015 EWHC 4306* following representations from the parties. In respect of that case, the LQC adopted Mr. Shaw's wording that the Tribunal was entitled to *'fill a gap'* and can reach its own assessment without experts.

## The Tribunal's Analysis of the Evidence and Findings

22. The Tribunal has considered each outstanding paragraph of the Allegation separately and has evaluated the evidence in order to make its findings on the facts.

Paragraph 3

23. The Tribunal considered that Dr Baxter had agreed a written Plea Agreement, pleaded guilty and been convicted at a remote court hearing on 31 August 2020. He was sentenced on 17 December 2020 and self-referred to the GMC on 11 January 2021.

24. In reaching its determination, the Tribunal was mindful of paragraph 75 of GMP, which states:

> *75 You must tell us without delay if, anywhere in the world:*
>
> *a you have accepted a caution from the police or been criticised by an official inquiry*
> *b you have been charged with or found guilty of a criminal offence*
> *c another professional body has made a finding against your registration as a result of fitness to practise procedures.*

25. The Tribunal was also mindful of the wording on the GMC self-referral form:

> *'When you should refer yourself to us*
> *You need to refer yourself to us if you:*
> *• may pose a risk to patients because you are not receiving or complying with the necessary treatment for a health condition (including alcohol or drug dependency) or do not have arrangements in place to manage your practice safely while you recover*

- *are under investigation by the police or given a caution or conviction*
- *have been sanctioned or criticised by another regulatory body, in the UK or abroad.'*

26. The Tribunal noted paragraph 4(c) of the GMC guidance document *'Reporting criminal and regulatory proceedings'*:

*'4 You must tell us without delay if, anywhere in the world, you:*

*…*

*c formally admit to committing a criminal offence (for example, by accepting a caution,[2] a community resolution order, in Northern Ireland a discretionary disposal, or a diversionary option such as an informed warning or caution, or in Scotland a fiscal fine, or by entering into a contractual disclosure facility agreement with HM Revenue and Customs, which involves admitting you have committed fraud)'*

27. In reaching its determination, the Tribunal only relied upon GMP.

28. Whilst GMP does not make reference to being arrested, being under investigation, being released on bail or cover the DOJ/US jurisdiction and procedures (such as a written Plea Agreement), the Tribunal considered that it sets out clearly a practitioner's obligation to report criminal charges to the GMC.

29. The Tribunal also had regard to the summary of US proceedings, which included the following paragraph:

*'On August 31, 2020, in a remote proceeding, Dr. Baxter entered his guilty plea to the crime of RCO misdemeanour misbranding based on (only) the facts as set forth in the Information. Before accepting Dr. Baxter's plea, the judge reviewed the Information, asked Dr. Baxter the necessary questions to confirm his understanding of the crime and his mental capacity to enter a plea, asked the prosecution about the Plea Agreement and to "set forth any facts or make a representation of the facts that the government would be prepared to prove if the case went to trial." In response, the prosecution responded simply "that the government would be prepared to prove the facts set forth in the Information and will rely on the Information for that." The judge then confirmed that Dr. Baxter was familiar with the facts as set forth in the Information and asked him whether he contested any of those facts. He replied that he did not. On that basis, the court then put the count to Dr. Baxter and accepted his guilty plea as deliberate,*

*voluntary and informed and as "supported by an independent basis in fact as to each of the essential elements of the offense charged."'*

30. The Tribunal noted the submissions made on behalf of Dr Baxter. It was submitted he was not charged until the formal sentencing hearing on 17 December 2020 (and that he reported to the GMC shortly thereafter on 11 January 2021). He had signed a written Plea Agreement in August 2020. It was asserted that these agreements serve as preliminary agreements between the prosecutor and the accused on the pleas to charges and may not be accepted.

31. The Tribunal did not accept that Dr Baxter was not formally charged until December 2020. It considered that the Information and signed Plea Agreement, formally admitted by Dr Baxter on 31 August 2020, constituted a formal conviction, which was ultimately confirmed at the sentencing hearing in December 2020.

32. The Tribunal noted that Dr Baxter asserted that he had discussed the ongoing criminal/legal matters with his Responsible Officer at the time but considered that although his Responsible Officer could have referred the matter to the GMC it was not their responsibility to do so. It was of the view that it was Dr Baxter's responsibility as a registered doctor to understand his obligations within GMP. It was clear that he should, at the least, have informed the GMC of his plea and conviction in August 2020, contacting the GMC if he was unsure whether or not the matters subject to court proceedings yet met the threshold for referral.

33. The Tribunal applied the ordinary, plain English definition of *'without delay'* as meaning *'right away, immediately, promptly'* and *'as soon as reasonable/reasonably practical'*. Having determined that Dr Baxter was charged, and had pleaded guilty on 31 August 2020, it considered whether his self-referral on 11 January 2021 constituted a delay under GMP. It concluded that the four and a half month period between Dr Baxter being charged and his self-referral did indeed constitute a delay because he had failed to inform the GMC right away or immediately.

34. Accordingly, the Tribunal found this paragraph of the Allegation proved.

<u>The fourth Paragraph</u>

35. When considering whether the offence committed at paragraph 1, if committed in England and Wales, would constitute a criminal offence the Tribunal adopted a narrow approach as determined in Annex B. The Tribunal applied the ordinary, natural meaning

to criminal offence and considered whether the US conviction would constitute an action or omission which would be punishable by law in England and Wales.

36. The Tribunal considered the submissions of Mr Shaw both orally and in his skeleton argument dated 19 June 2023. The Tribunal considered the refined submissions of Ms Beattie, made orally focusing on the Business Protection from Misleading Marketing Regulations 2008, ('the 2008 regulations') and her skeleton argument dated 20 June 2013.

37. The relevant sections of the 2008 Regulations are:

*'2.— (1) In these Regulations—*
*"advertising" means any form of representation which is made in connection with a trade, business, craft or profession in order to promote the supply or transfer of a product and "advertiser" shall be construed accordingly;*

*…*

*3.— (1) Advertising which is misleading is prohibited.*
*(2) Advertising is misleading which—*

*(a) in any way, including its presentation, deceives or is likely to deceive the traders to whom it is addressed or whom it reaches; and by reason of its deceptive nature, is likely to affect their economic behaviour; or*

*(b) for those reasons, injures or is likely to injure a competitor.*

*…*

*6. A trader is guilty of an offence if he engages in advertising which is misleading under regulation 3.*

*…*

*8.— (1) Where an offence under these Regulations committed by a body corporate is proved—*

*(a) to have been committed with the consent or connivance of an officer of the body, or*
*(b) to be attributable to any neglect on his part, the officer as well as the body corporate is guilty of the offence and liable to be proceeded against and punished accordingly.*

*(2) In paragraph (1) a reference to an officer of a body corporate includes a reference to—*

*(a) a director, manager, secretary or other similar officer; and*

*(b) a person purporting to act as a director, manager, secretary or other similar officer.'*

38. The Relevant sections of the US law, which Dr Baxter was convicted under, are:

*'21 U.S.C. §331(a).*

*Under 21 U.S.C. §333(a)(1) and applicable case law, a responsible executive with authority to either prevent in the first instance or to promptly correct certain conduct resulting in the misbranding of a drug introduced or delivered for introduction into interstate commerce may be liable for a misdemeanor violation of 331(a). The FDCA provides that a drug is misbranded if, among other things, its labelling is 'false or misleading in any particular.'*

*21 U.S.C. §352(a). 'Labeling' includes 'brochures, booklets … letters … exhibits [and] literature … descriptive of a drug whether or not it physically accompanies the drug when distributed. See U.S.C. §321(m); 21 C.F.R. §202.1(1)(2). Considering whether labelling is misleading requires assessing 'the extent to which the labelling … fails to reveal facts' that are 'material' in light of 'representations made or suggested by statement, word, design, device, or any combination thereof.'*

39. The Tribunal also specifically referred to the material that had been adjudicated and/or admitted in the US convictions and contained in Dr Baxter's witness statement dated 18 August 2022, made for these proceedings.

40. The Tribunal reminded itself that it was not seeking an exact match for the offence but a comparable offence. In this case the GMC had been required to 'stick their colours to the mast' and define what that offence might be.

41. The Tribunal was satisfied that the definition of advertising in Regulation 2(1) and the prohibitions in Regulation 3(2) are analogous to the broad labelling description in the US offence.

42. The representations made by Indivior to MassHealth in respect of the RADAR research was advertising for the purposes of the 2008 Regulations because it was *'a representation in connection with a trade in order to promote the supply…of a product',* in this case Suboxone film.

43. The representations were intended to affect economic behaviour i.e. to persuade MassHealth to provide Suboxone film on Medicaid, rather than the tablet form. Indivior would also extend their *'exclusivity'* through the adoption of the film rather than the tablet form, which may negatively impact or be likely to injure competitors. The Tribunal understood exclusivity to mean a period of seven years during which the US Food and Drug Administration was prohibited from approving any competing applications for the same drug.

44. The US offences, in common with offences affecting directors in English and Welsh legislation, involved the conviction of Indivior in November 2020 and provides for the prosecution of officers. The sections and wording of the offence in the 2008 Regulations reflect this: Regulation 8 provides that where a company is convicted of the same offence, an officer (director, manager or other similar officer) may be convicted where he consented or connived with the company in its commission or where the commission of the offence was attributable to any neglect on his part.

45. The Tribunal first considered the Information to which Indivior pleaded guilty to determine if this was substantively the same offence as that to which Dr Baxter pleaded guilty.

46. The Tribunal therefore analysed the agreed facts and that which had been adjudicated in the US case to determine whether the offence, while a strict liability offence requiring no proof of intention, had been committed through neglect. The Tribunal gave neglect its ordinary and natural meaning: failing to give proper care or attention to something.

47. The Tribunal considered the elements of the offences to which both Dr Baxter and Indivior had pleaded guilty in respect of the representations (accepted as a misrepresentations in the US sentencing) made to MassHealth.

48. The Tribunal noted paragraph 17 of Dr Baxter's witness statement in which he detailed his role at Indivior:

> *'While I did not have the authority to make commercial decisions, I did advise commercial decision-makers regarding medical issues and patient safety. As a member*

*of RBP's Global Leadership Team, I provided medical advice in support of the company's research and development efforts; including for a new product called Suboxone Film…'*

49. Dr Baxter had been closely involved in instructing RADARS and had been copied in to the results. He noticed the discrepancy in the result, i.e. that the mono-tablet form presented the lowest paediatric ingestion risk and he emailed the MAM straight back to identify that. He was also aware that the MAM, who reported to him, intended to combine the figures to alter the import of the data to help *'get some movement in Mass.*'

50. It is not asserted, and there is no evidence, that Dr Baxter, having noticed the actual results and having pointed this out via email to the MAM, ever followed up with either her or the sales team. This would have ensured that this representation was corrected. Rather, he condoned the sales team using a chart which left out relevant data. This was particularly referred to by the sentencing Judge who noted that the data presented to MassHealth was false and misleading and that Dr Baxter had failed to prevent its publication.

51. The Tribunal found that there was an inevitable inference to be drawn that Dr Baxter's failure to prevent and promptly correct the false and misleading data and marketing claims amounted to neglect.

52. The Tribunal noted that the same facts are agreed in the Information in respect of the conviction of Indivior and Dr Baxter, and both were convicted for failing to correct the same false and misleading statements to MassHealth. The Tribunal recognised that the charge was under a different section for the company because it included the profit element, i.e. the payment for Suboxone Film, which the responsible officer offence does not.

53. While the offences are not identical in wording, the Tribunal found on the adjudicated and agreed facts of the US case and the witness statement evidence of Dr Baxter that the offence to which he had pleaded guilty in the US would be a criminal offence in England and Wales.

## The Tribunal's Overall Determination on the Facts

54. The Tribunal has determined the facts as follows:

That being registered under the Medical Act 1983 (as amended):

1. On 17 December 2020, at the United States District Court Western District of Virginia, you were convicted of causing the introduction or delivery for introduction into interstate commerce of a drug that is misbranded, contrary to Title 21 of the United States Code, Sections 331(a) and 333(a)(1). Admitted and found proved

2. On 17 December 2020, at the United States District Court Western District of Virginia, you were sentenced inter alia to: Amended under Rule 17(2)(c)

    a. pay a fine of $100,000.00; Admitted and found proved

    b. one year probation. Admitted and found proved

3. You failed to notify the General Medical Council without delay that you had formally admitted to the criminal offence outlined at paragraph 1. Determined and found proved

The offence outlined at a paragraph 1, if committed in England and Wales, would constitute a criminal offence (see Annex A). Determined and found proved

And that by reason of the matters set out above your fitness to practise is impaired because of your:

a. conviction in relation to paragraphs 1 and 2; To be determined

b. misconduct in relation to paragraph 3. To be determined

## Determination on Impairment - 29/06/2023

55. The Tribunal now has to decide in accordance with Rule 17(2)(l) of the Rules whether, on the basis of the facts which it has found proved as set out before, Dr Baxter's fitness to practise is impaired by reason of conviction and/or misconduct.

## The Evidence

56. The Tribunal has taken into account all the evidence received during the facts stage of the hearing, both oral and documentary.

57. In addition, the Tribunal received four testimonials from colleagues in support of Dr Baxter, all of which it has read.

58. The Tribunal also received details of Dr Baxter's appraisals between 2014 and 2021, CPD certificates and documents relating to remediation and reflection referred to in Dr Baxter's Responsible Officer's statement.

## Submissions

59. On behalf of the GMC, Ms Beattie, KC, submitted that, when considering impairment, a doctor's ability to practise was not the only concern but also whether the doctor is suitable to practise. She submitted that it was open for the Tribunal to find that Dr Baxter's fitness to practise is impaired if it considered that his previous conduct brought the suitability of his fitness to practise into question.

60. Ms Beattie reminded the Tribunal that Dr Baxter's fitness to practise may be found to be impaired on grounds of either his misconduct or his conviction or both.

61. Ms Beattie acknowledged that there were no patient safety concerns in this case, submitting the interests of professional standards and, in particular, public confidence must be considered. She referred the Tribunal to the case of *R(On the application of Harry) v General Medical Council [2006] EWHC 3006*:

> *'In deciding whether there has been misconduct, it is not possible, in my view, to ignore the public interest in the wider sense. That interest is an integral aspect when deciding whether the particular facts proved have passed the threshold and amount to misconduct.'*

62. Ms Beattie referred the Tribunal to relevant caselaw, including the cases of *Cohen v General Medical Council [2008] EWHC 581 (Admin), Remedy UK Ltd, R (on the application of) v The General Medical Council [2010] EWHC 1245 (Admin) (28 May 2010) and Cheatle v General Medical Council [2009] EWHC 645 (Admin) (27 March 2009).* Ms Beattie also set out Dame Janet Smith's test for impairment in The Fifth Shipman Report, cited in *CHRE v NMC and P Grant [2011] EWHC 927 (Admin):*

> *'a) Whether the registrant has in the past acted and/or is liable in the future to act so as to put a patient or patients at unwarranted risk of harm;*

*b) Whether the registrant has in the past brought and/or is liable in the future to bring the profession into disrepute;*

*c) Whether the registrant has in the past breached and/or is liable in the future to breach one of the fundamental tenets of the profession.*

*d) Whether the registrant has in the past acted dishonestly and/or is liable to act dishonestly in the future.'*

63. Ms Beattie submitted that although the events leading to Dr Baxter's conviction in the US took place over ten years ago, the Tribunal should still look at his level of insight and remediation. She submitted that Dr Baxter had shown a pattern of minimising behaviour where he sought to shift blame on to others and reduce the level of responsibility that he bore.

64. Ms Beattie told the Tribunal that both Good Medical Practice (2013) ('GMP') and its previous edition were relevant as Dr Baxter's conduct spanned both versions. She set out various paragraphs of the old edition of GMP, which she submitted that Dr Baxter had breached, as well as their comparable paragraphs from the 2013 edition. She submitted that the relevant paragraphs of the 2013 edition were:

*'40 You must make sure that all staff you manage have appropriate supervision.*

*…*

*65 You must make sure that your conduct justifies your patients' trust in you and the public's trust in the profession.*

*…*

*67 You must act with honesty and integrity when designing, organising or carrying out research, and follow national research governance guidelines and our guidance*

*68 You must be honest and trustworthy in all your communication with patients and colleagues. This means you must make clear the limits of your knowledge and make reasonable checks to make sure any information you give is accurate*

*…*

*70 When advertising your services, you must make sure the information you publish is factual and can be checked, and does not exploit patients' vulnerability or lack of medical knowledge.*

*71 You must be honest and trustworthy when writing reports, and when completing or signing forms, reports and other documents.[22] You must make sure that any documents you write or sign are not false or misleading.*

*a You must take reasonable steps to check the information is correct.*

*b You must not deliberately leave out relevant information*

*75 You must tell us without delay if, anywhere in the world:*

*a you have accepted a caution from the police or been criticised by an official inquiry*

*b you have been charged with or found guilty of a criminal offence*

*c another professional body has made a finding against your registration as a result of fitness to practise procedures'*

65. Ms Beattie told the Tribunal that Dr Baxter's case was that his conviction was a result of the MAM's actions. However, Ms Beattie submitted that GMP is clear in how a doctor should behave and, being in a position of authority and responsibility, it was incumbent on Dr Baxter to comply with the above paragraphs of GMP and prevent the miscommunications to MassHealth. Ms Beattie submitted that Dr Baxter's statements regarding the responsibility of the MAM ignored the fundamental duties that fell upon him under GMP.

66. Ms Beattie submitted that Dr Baxter's Witness Statement showed a lack of insight: he did not offer an analysis of his actions, how he failed or what he could do differently in the future. She said that his focus was on stressing that his conviction was for a less serious offence, that of a misdemeanour rather than a felony, and he did not reflect on how he had not complied with his obligations.

67. Ms Beattie submitted that Dr Baxter's exclusion from access to public funding demonstrated the seriousness with which public bodies regard his conviction.

68. Ms Beattie asked the Tribunal to consider what the UK public would consider of a doctor who had been convicted of an offence involving mislabelling a drug and misrepresenting its efficacy. She submitted that this offence goes to the heart of the public confidence

limb of the overarching objective as the public expect doctors to comply with regulations and would find Dr Baxter's overall conduct to be egregious.

69. Ms Beattie also submitted that delaying informing the GMC of his conviction represented a serious departure from the principles of GMP set out above. She said that there was no good reason for Dr Baxter to have delayed and he was aware of his obligation to do so.

70. Ms Beattie submitted that, in conclusion, the Tribunal should find that Dr Baxter's fitness to practise is impaired because of the seriousness of his offence, his lack of insight and remediation, and his serious misconduct in failing to report his conviction to the GMC. She submitted that the Tribunal's duty under the public interest limb of the overarching objective required a finding of impairment.

71. On behalf of Dr Baxter, Mr Shaw, KC, accepted the references of Ms Beattie to the cases of *Roylance, Remedy* and *Grant*. He also directed the Tribunal to the GMC guidance document *The Meaning of Fitness to Practise (February 2021)* and asked it to consider the following:

> *'5. All human beings make mistakes from time to time. Doctors are no different. While occasional one-off mistakes need to be thoroughly investigated by those immediately involved where the incident occurred and any harm put right, they are unlikely in themselves to indicate a fitness to practise problem. Good medical practice puts it this way:*
>
> *6. 'Serious or persistent failures to follow this guidance will put your registration at risk'.'*

72. Mr Shaw submitted that Dr Baxter's conduct leading to these proceedings was not serious or persistent and arose from a single episode, which was made clear throughout his statement and the testimonials. Mr Shaw said that Dr Baxter's conviction was the sole blemish on an otherwise long and distinguished career and the guidance above showed that his fitness to practise should not be found impaired.

73. Mr Shaw reminded the Tribunal that the events leading to Dr Baxter's conviction took place over ten years ago and there had never been any other concerns raised. He submitted that there was no risk of Dr Baxter repeating his conduct and the sentencing judge had said there were no concerns about repetition. Mr Shaw submitted that, as a strict liability offence, Dr Baxter's integrity had not been brought into question and , in any case, he was no longer in a comparable role in which to repeat his actions.

74. Mr Shaw refuted Ms Beattie's submission that Dr Baxter lacked insight or had sought to deflect blame onto someone else. He drew the Tribunal's attention to Dr Baxter's statement and appraisals and submitted that these clearly showed Dr Baxter acknowledging his responsibility as a senior manager. Mr Shaw also said that, where Dr Baxter had apportioned blame to the MAM, he was right to do so. Mr Shaw submitted that although Dr Baxter could have done more to stop the misrepresentations made to MassHealth, he had put trust in the MAM and been deceived by her just as MassHealth had been.

75. Mr Shaw submitted that public confidence would not be harmed if the Tribunal did not make a finding of impairment. He said that a member of the public, apprised of all the circumstances of the facts, may think that Dr Baxter could have done more but would understand that he did make attempts to check the information being shared and was untruthfully reassured by the MAM. Mr Shaw said that Dr Baxter accepts he should have done more to check and that this formed part of his reason for accepting responsibility as a supervisor.

76. Mr Shaw submitted that Dr Baxter's offence did not involve any harm coming to patients or other end users, that he took steps to correct the mistake as soon as he learned about it and that MassHealth did not change their policy regarding Suboxone Film after the misrepresentations were revealed. Mr Shaw said that this final point demonstrated that Indivior's economic affairs were not impacted by the misrepresentations.

77. Mr Shaw told the Tribunal that Dr Baxter completed his sentence without complaint and found the experience to be valuable and instructive. Dr Baxter had been prompted to reflect on events because of his sentence and had gained perspective on his role and how he could avoid a similar thing happening in the future. Mr Shaw submitted that this demonstrated Dr Baxter's mature, conscientious and regretful attitude, which his RO had echoed in her statement. Mr Shaw submitted that it was difficult to conceive what more Dr Baxter could do to demonstrate or improve his insight.

78. Turning to the reporting delay, Mr Shaw submitted that this was an unintentional mistake with no attempt at concealing. He said that Dr Baxter understood that his obligation to contact the GMC was crystalised at the point of his conviction in December 2020. Mr Shaw told the Tribunal that Dr Baxter had undertaken remediation on the importance of being forthright and reporting things promptly and submitted that this issue was not serious enough for a finding of impairment.

## The Relevant Legal Principles

79. The Tribunal reminded itself that at this stage of proceedings, there is no burden or standard of proof and the decision of impairment is a matter for the Tribunal's judgement alone.

80. In approaching the decision, the Tribunal was mindful of the two-stage process to be adopted: first whether the facts as found proved amounted to misconduct and that the misconduct was serious. Then, whether the finding of that misconduct, which was serious, and the conviction could lead to a finding of impairment.

81. The Tribunal must determine whether Dr Baxter's fitness to practise is impaired today, taking into account his conduct at the time of the events and any relevant factors since then such as whether the matters are remediable, have been remedied and any likelihood of repetition.

82. The Tribunal was mindful of the Dame Janet Smith's test set out in *Grant* above as well as the following principle:

> *'74 In determining whether a practitioner's fitness to practise is impaired by reason of misconduct, the relevant panel should generally consider not only whether the practitioner continues to present a risk to members of the public in his or her current role, but also whether the need to uphold proper professional standards and public confidence in the profession would be undermined if a finding of impairment were not made in the particular circumstances.'*

## The Tribunal's Determination on Impairment

Misconduct

83. The Tribunal began by considering if Dr Baxter's delay in informing the GMC of his conviction amounted to misconduct.

84. The Tribunal bore in mind paragraph 75 of GMP, as set out above, and noted that the word *'must'* indicated an overriding duty upon a doctor. Having previously found that Dr Baxter did not report his conviction without delay, the Tribunal considered that this constituted a serious breach of GMP.

85. The Tribunal considered that Dr Baxter had a duty to comply with GMP and had known about his conviction from August 2020 – four and a half months before he informed the GMC.

86. Therefore, the Tribunal concluded that Dr Baxter's conduct fell so far short of the standards of conduct reasonably to be expected of a doctor as to amount to misconduct.

87. The Tribunal having found that the facts found proved amounted to misconduct, went on to consider whether, as a result of that misconduct, Dr Baxter's fitness to practise is currently impaired.

88. The Tribunal took into account the circumstances surrounding Dr Baxter's delay in reporting to the GMC. It noted that he had informed his RO but not the GMC. He did in fact self-refer. The Tribunal considered that it was Dr Baxter's responsibility to check if he needed to inform the GMC of his criminal proceedings but accepted the submission that he had not sought to conceal them.

89. The Tribunal considered that Dr Baxter had failed to uphold proper professional standards with regards his reporting. However, it did not consider this failure to be so serious as to require a finding of impairment. The Tribunal also considered that the public interest did not require a finding of impairment regarding this aspect of the case as a member of the public would not consider a four-month delay, in these circumstances, so serious that Dr Baxter's registration needed to be marked.

Conviction

90. The Tribunal then went on to consider if Dr Baxter's fitness to practise is currently impaired because of his conviction.

91. The Tribunal reminded itself of the case of *Meadow*, as referred to by Ms Beattie:

> *'the purpose of FTP proceedings is not to punish the practitioner for past misdoings but to protect the public against the acts and omissions of those who are not fit to practise. The FPP thus looks forward not back. However, in order to form a view as to the fitness of a person to practise today, it is evident that it will have to take account of the way in which the person concerned has acted or failed to act in the past.'*

92. The Tribunal took account of the length of time since the events that led to Dr Baxter's conviction and accepted Mr Shaw's submission that there had been no other concerns in

that time. The Tribunal was conscious that its role was not to punish Dr Baxter for a second time and accepted that Dr Baxter had served his sentence and been changed by it. In particular, the Tribunal noted the real impact of Dr Baxter being restricted from public funding.

93. The Tribunal reminded itself that although patient safety was not a concern in this case it may need to make a finding of impairment to maintain public confidence in the profession and uphold proper professional standards.

94. The Tribunal reminded itself that it had previously found Dr Baxter's actions to be neglectful not dishonest. He had accepted his responsibility and punishment for his offence. The Tribunal considered that, bearing in mind the length of time since the events and the nature of the conviction, the issue of Dr Baxter's insight and remediation was key.

95. The Tribunal turned to the parts of the evidence that it had been directed to by the parties. The Tribunal considered how this evidenced insight, changes in practise and remediation.

96. The Tribunal noted the following passages from Dr Baxter's 2014 and 2021 appraisals:

2014 appraisal: *'As a member of the Corporate leadership I carry managerial responsibility for any significant events whether or not I am specifically named. However, if the investigation is over a compliance issue, whether I am named or not, I would bear managerial responsibility.'*

2021 appraisal: *'.....the information he has provided about how he has dealt with the case and sentencing provide compelling evidence to support his integrity. In our discussions TB demonstrated a high level of awareness of the trust that is placed on medical practitioners and acceptance of the rule of corporate officer responsibility under US law. TB has provided evidence that he has reported the events to the RO and GMC and is awaiting the outcome of the GMC investigation'.*

97. The Tribunal also noted Dr Baxter's statement in his reflection on regret for his conviction:

*'Whilst I was not aware of the events resulting in the misbranding, it did occur within my reporting line. I regret that I was not more vigilant in policing the activities of my subordinates. In future, should I be in a position of having responsibility for the activities*

*of others, I will be more diligent in monitoring the activities of my reports, not matter how trusted, highly experienced, or well trained.'*

98. The Tribunal gave particular weight to the testimonial of Dr B where he said:

*'My sense is that this experience has left a deep mark on Tim. He gives me the impression still of being very shocked and disappointed by all that took place, whilst having taken the punishment with much modesty and humility. I suspect, if he were ever to be in the same situation again, he would double and triple check what was going on in any team beneath him and regularly and actively seek re-assurance that all was operating as it should. I don't think he would take anything for granted.'*

99. The Tribunal considered that these extracts demonstrated that Dr Baxter had reflected and developed insight. It found that Dr Baxter had accepted that he had ultimate responsibility, had apologised and expressed regret. And, he had accepted with hindsight he would have acted differently. The Tribunal did not accept Ms Beattie's submission that Dr Baxter had not reflected on what went wrong or what he could do differently in the future.

100. The Tribunal accepted that Dr Baxter now works in a consultancy practice and he no longer has broad management of others in this work.

101. The Tribunal took into account the CPD Dr Baxter had undertaken and particularly his reflection on training and ethics and professional standards for doctors.

102. As with the misconduct allegation, the Tribunal considered Dr Baxter's conviction to represent a serious departure from GMP, as set out by Ms Beattie. However, the Tribunal accepted that this was a one-off event and turned to *The Meaning of Fitness to Practise* document referred to by Mr Shaw:

*'All human beings make mistakes from time to time. Doctors are no different.'*

103. In conclusion, the Tribunal was satisfied that, in all the circumstances of the case, there was no risk of Dr Baxter repeating his actions and that it was not necessary to find his fitness to practise impaired to satisfy either the public interest or the need to uphold proper professional standards.

104. The Tribunal therefore determined that Dr Baxter's fitness to practise is not impaired.

105. As the Tribunal determined that Dr Baxter's fitness to practise was not impaired, it considered whether, in accordance with s35D(3) of the 1983 Act, a warning was required.

## Submissions

106. On behalf of the GMC, Ms Beattie, KC, submitted the Tribunal's previous findings that Dr Baxter had committed a serious breach of GMP meant it would be appropriate to issue a warning in this case. She reminded the Tribunal that it had made this finding with regard to both Dr Baxter's conviction and his failure to report this without delay.

107. Ms Beattie reiterated that the Tribunal had found both Dr Baxter's conviction and failure to report to the GMC to be serious breaches of GMP. She submitted that these serious breaches needed to be formally marked with a warning to uphold public confidence in the profession and send a message to the profession at large about maintaining proper professional standards.

108. Ms Beattie referred the Tribunal to the Guidance on Warnings (2021) ('the GW'). She said that this guidance sets out that a warning can be used to indicate to a doctor, the profession and the public that *'…any given conduct, practice or behaviour represents a departure from the standards expected of members of the profession and should not be repeated.*'

109. Ms Beattie submitted that paragraph 20(a) of the GW indicates that a warning would be appropriate in this case because of the Tribunal's findings at the impairment stage:

> *'20 The decision makers should take account of the following factors to determine whether it is appropriate to issue a warning.*
>
> *a There has been a clear and specific breach of Good medical practice or our supplementary guidance.'*

110. On behalf of Dr Baxter, Mr Shaw, KC, submitted that it was not necessary to issue a warning to Dr Baxter. He referred the Tribunal to paragraph 65 of the Sanctions

Guidance (2020) ('the SG'), which sets out that the Tribunal must give clear reasons why it is issuing a warning or not. Mr Shaw submitted that it would not be possible for the Tribunal to comply with this paragraph because there were no good reasons to impose a warning in this case.

111. Mr Shaw submitted that there was no value in a signal sent by a warning because Dr Baxter had already been profoundly affected by his conviction and the hearing process. He told the Tribunal that Dr Baxter already understood the seriousness of his departures from GMP and a warning would not add to this. Mr Shaw also submitted that the deterrent effect of a warning would not have any effect because Dr Baxter was no longer in a position to repeat the conduct that led to his conviction.

112. Mr Shaw referred the Tribunal to paragraph 32 of the GW, which sets out factors to help determine if a warning is appropriate. He submitted that the Tribunal would find Dr Baxter had positively complied with each of these factors:

*'a the level of insight into the failings*

*b a genuine expression of regret/apology*

*c previous good history*

*d whether the incident was isolated or whether there has been any repetition*

*e any indicators as to the likelihood of the concerns being repeated*

*f any rehabilitative/corrective steps taken*

*g relevant and appropriate references and testimonials.'*

## The Tribunal's Determination on Warning

113. The Tribunal accepted that Dr Baxter had demonstrated insight and remediation but reminded itself of the serious nature of his conduct and departure from GMP.

114. The Tribunal noted Mr Shaw's submission that Dr Baxter understood the seriousness of his misconduct but considered that the purpose of a warning went beyond sending a

message to Dr Baxter. The Tribunal considered that there was significant public interest in signalling to the profession as a whole the seriousness of Dr Baxter's misconduct and departure from GMP.

115. The Tribunal had regard to paragraph 14 of the GW:

> *'Warnings should be viewed as a deterrent. They are intended to remind the doctor that their conduct or behaviour fell significantly below the standard expected and that a repetition is likely to result in a finding of impaired fitness to practise. Warnings may also have the effect of highlighting to the wider profession* [and the public] *that certain conduct or behaviour is unacceptable.'*

116. The Tribunal was satisfied that Dr Baxter had made serious departures from GMP regarding both his conviction and his failure to inform the GMC without delay. This conduct fell significantly below the standard expected of a doctor. It considered that these failures would have a substantial impact on public confidence and the reputation of the profession.

117. The Tribunal reminded itself of the overarching objective of protecting the public. It considered that its duty to uphold and maintain public confidence in the profession meant that it was appropriate to issue a warning in this case. It also considered that a warning was necessary to send a message to the profession about maintaining proper professional standards.

118. The Tribunal therefore determined to issue the following warning in accordance with Section 35D(3) of the Medical Act 1983 and Rule 17(2)(n) of the Rules:

> 'Dr Timothy Baxter
>
> On 17 December 2020, at the United States District Court Western District of Virginia, you were convicted of causing the introduction or delivery for introduction into interstate commerce of a drug that is misbranded, contrary to Title 21 of the United States Code, Sections 331(a) and 333(a)(1). You were sentenced inter alia to pay a fine of $100,000 and serve one year of probation. This offence, if committed in England and Wales, would constitute a criminal offence pursuant to the Business Protection from Misleading Marketing Regulations 2008; [Regulation 2, 2(1), 3, 6, 8(1) and 8(2)].

You also failed to inform the GMC of this conviction without delay.

This conviction and conduct do not meet with the standards required of a doctor. The misconduct risks bringing the profession into disrepute and it must not be repeated. The required standards are set out in *Good medical practice* and associated guidance. In this case, paragraphs 65 and 71 of GMP are particularly relevant:

> *'65 You must make sure that your conduct justifies your patients' trust in you and the public's trust in the profession.*
>
> *71 You must be honest and trustworthy when writing reports, and when completing or signing forms, reports and other documents. You must make sure that any documents you write or sign are not false or misleading.*
>
> *a You must take reasonable steps to check the information is correct.*
>
> *b You must not deliberately leave out relevant information.'*

Whilst this failing in itself is not so serious as to require any restriction on your registration, it is necessary in response to issue this formal warning.

This warning will be published on the medical register in line with our publication and disclosure policy, which can be found at www.gmc-uk.org/disclosurepolicy.'

119.This concludes the case.

ANNEX A: Application to admit further evidence – 29/06/2023

120. On day one of the hearing Ms Beattie, KC, made an application pursuant to Rule 34(1) of the Fitness to Practise Rules (2004) as amended ('the Rules') to admit further evidence relating to the conviction of Indivior itself and another responsible officer.

Submissions

121. On behalf of the GMC, Ms Beattie, KC, submitted that the Supplementary Bundle was relevant to the case because it dealt with the related convictions of Indivior and the other responsible officer. She said that all the materials went to the same point, that of false statements made to MassHealth, which she said Dr Baxter had also made.

122. Ms Beattie told the Tribunal that there had been disagreement between the parties about whether the Information was the only document that was relied upon at sentencing and submitted that, in the US and as far as the District Attorney was concerned, all material was relevant. She submitted that the same was true at this hearing.

123. Ms Beattie submitted that the case against Dr Baxter in the US was made up of more than just the Information as there was also the evidence that was garnered in order to make up the Information, and that was relevant for this hearing.

124. On behalf of Dr Baxter, Mr Shaw, KC submitted that the content of most of the documents that had been submitted were irrelevant, controversial and uncertain. He told the Tribunal that it was true that these two cases were related to Dr Baxter's, but only in a very broad sense. He said that it is plain that the matters are related by the underlying facts but that the Tribunal should only concern itself with information relating directly to Dr Baxter's conviction.

125. Mr Shaw submitted that it was not enough for Ms Beattie to say that the materials could help the Tribunal to draw inferences, she must explain how and why they are relevant to this case.

126. Mr Shaw directed the Tribunal to section 35(c)(2)(c) of the Medical Act 1983 and submitted that this does not refer to sentencing, only the offence. Therefore, he submitted, the Tribunal should only be considering materials relating to Dr Baxter's

conviction, not his sentence, as those materials did not assist in determining Dr Baxter's guilt, only the severity of his sentence. Mr Shaw submitted that the record of conviction and the Information were the primary documents that the Tribunal should be concerned with and that Dr Baxter's sentencing memoranda should be removed from evidence.

## Legal Principles

127. The LQC referred the Tribunal to Rule 34(1) of the Rules and set out that this was the test to be applied:

> *'The Committee or a Tribunal may admit any evidence they consider fair and relevant to the case before them, whether or not such evidence would be admissible in a court of law.'*

128. The LQC remined the Tribunal that its role was not to re-try the US case or hold a Newton hearing, but to confine itself to the facts of the conviction.

## The Tribunal's Determination

129. The Tribunal reminded itself that in a conviction case the production of a certificate purporting to be under the hand of a competent officer of a Court in the United Kingdom or overseas that a person has been convicted of a criminal offence or, in Scotland, an extract conviction, shall be conclusive evidence of the offence committed.

130. The Tribunal reminded itself that relevance could be determined by considering whether the evidence was probative of a fact in issue or supports or contradicts an argument or proposition that enables a party to prove its own case or to disprove their opponent's.

131. The Tribunal restricted itself to admitting that evidence which would enable the Tribunal to decide the charges before it. The Tribunal noted that the timetable within which to specify the evidence upon which the parties rely, Rule 34(9), had not been complied with.

132. The Tribunal took a preliminary view to examine the records of conviction for Indivior and the other responsible officer and then decide if the documents in question were relevant to the task of assessing if there is a comparable offence in England and Wales to that which Dr Baxter was convicted. The Tribunal was mindful that it should only be

considering the conduct of Dr Baxter and not that of other parties. The Tribunal was satisfied that this approach would be fair to both parties.

133. Having seen the Judgement of Criminal Case Documents, which are analogous to a Record of Conviction, the Tribunal was in a position to assess their relevance to the case.

134. The Tribunal considered that a live issue, raised in the documents, was the conviction of Indivior and another responsible officer. The facts and particulars of these convictions was evidence on which both parties could put their respective cases on section 35(c)(2)(c). The Tribunal therefore determined that the evidence was relevant and the admission of this evidence was fair, balancing the interests of both the parties. The admission of these documents enabled both parties to fairly put their case in respect of the fourth paragraph of the allegations.

135. However, the Tribunal determined that it did not need to see any other documents contained within the Supplementary Bundle. The Tribunal considered that it was only hearing the case of Dr Baxter, who committed a strict liability offence, and so it should not consider documents relating to other parties. The plea agreements, memoranda for sentencing and transcripts of hearings in respect of those other convictions were the facts behind Dr Baxter's conviction, which would not assist the Tribunal to decide the charges before it. The Tribunal reminded itself that, should the Information documents in respect of those convictions become relevant to determining section 35(c)(2)(c), these could be admitted into evidence.

136. The Tribunal found that the memoranda for sentencing were partisan documents submitted on behalf of the Government and the doctor as part of the sentencing process. These were specifically not adjudicated upon in the sentencing exercise by the US court and contained personal information about the defendants. That being the case, the Tribunal determined that these documents were not relevant to the facts in issue in this case and the admission of those documents may be prejudicial to the fairness of proceedings.

137. As a result of this decision, the Records of Conviction were admitted to evidence but the Memoranda of Sentencing, previously adduced, were deemed irrelevant. The Tribunal will put these other documents out of its mind during its considerations.

**ANNEX B: Application to determine the Tribunal's approach to the fourth paragraph of the Allegation –** 29/06/2023

138. On day two of the hearing, having determined what additional evidence was admissible, the Tribunal heard submissions from the parties on what approach it should take when considering the fourth paragraph of the Allegation. The fourth paragraph of the Allegation reads as follows:

> *'The offence outlined at a paragraph 1, if committed in England and Wales, would constitute a criminal offence (see Annex A).'*

139. The Tribunal must decide if, in determining whether this paragraph of the Allegation is true, it should consider Dr Baxter's conduct that led to his US conviction and if that conduct would be an offence in England and Wales, or if it should only consider the offence that Dr Baxter was convicted of and whether there is an equivalent offence in England and Wales.

**Submissions**

140. On behalf of the GMC, Ms Beattie, KC, said that having established which documents were to be relied upon throughout the case, the Tribunal must now decide how it should approach the issue of whether Dr Baxter's conduct amounts to an offence in England and Wales. She set out that the Tribunal must determine whether to assess paragraph 4 of the Allegation based on a test of Dr Baxter's conduct against English and Welsh law, or on a test of the equivalency of Dr Baxter's US conviction with a comparable offence in English and Welsh law.

141. Ms Beattie submitted that the legal authorities that she had provided to the Tribunal were important to consider, despite them being authorities on extradition law, because they identify that Dr Baxter's conduct should be considered, not just the fact of his conviction. She submitted that asking only if Dr Baxter's US offence equated to an offence in England and Wales created a significant barrier for the Tribunal to assess the seriousness of his conduct.

142. Ms Beattie submitted that the same actions conducted in different jurisdictions can lead to different legal outcomes. She told the Tribunal that a person convicted of a sexual offence in certain states in the US would not be convicted of such in England and Wales

because of the difference in the age of consent, even though the offence is comparable. Ms Beattie submitted that this demonstrated why the Tribunal must consider Dr Baxter's conduct and not just the offence for which he was convicted.

143. Ms Beattie referred the Tribunal to the case of *Cleveland v United States [2019] EWHC 619 (Admin)*, which she submitted set out that conduct must be considered:

> *'A number of relevant legal principles are well established. In Norris v Government of the United States of America [2008] AC 920 the House of Lords decided that a court should not consider whether the elements of the offence in an extradition request correspond with the elements of an English offence. Instead the court should consider whether the alleged conduct, if it had occurred in the United Kingdom, would amount to an offence under English law.'*

144. Ms Beattie submitted that Cleveland confirmed that any mens rea that was required for extradition could be established by 'drawing inferences capable of being drawn on the conduct alleged as opposed to being "inevitable" inferences'

145. On behalf of Dr Baxter, Mr Shaw, KC submitted that there was no analogue in England and Wales to the offence for which Dr Baxter was convicted. He said that all of his arguments lead back to this point: that there is a fundamentally different legal basis for the conviction under US law. In particular, that the offence for which Dr Baxter was convicted was a strict liability offence, meaning that there was no mental component to the offence but that this would be required in England and Wales.

146. Mr Shaw submitted that Dr Baxter was convicted in the US purely because of his position within Indivior, not because of his conduct. He said that this is an obvious and significant in the difference in the legal frameworks in the US and in England and Wales and that the Tribunal should not consider Dr Baxter's conduct in this case. Mr Shaw submitted that the Tribunal should only assess if the offence for which Dr Baxter was convicted has an equivalent offence in England and Wales.

147. Mr Shaw highlighted the words 'committed', 'criminal' and 'offence' in the Allegation and submitted that these were the three key words that the Tribunal should consider when making its decision on the approach to take in assessing paragraph 4 of the Allegation. He told the Tribunal that the key words in the US offence were 'responsible

executive' and 'authority'. Mr Shaw said that this demonstrated that the US offence was interested only in Dr Baxter's professional position, not his conduct.

148. Mr Shaw submitted that both section 35(c)(2)(c) of the Medical Act 1983 ('the Act') and the Allegation itself focussed on the word 'offence' rather than 'conduct' and that the Tribunal could use this as an indication that it should not consider Dr Baxter's conduct in relation to this matter.

149. Mr Shaw told the Tribunal that it was inappropriate to compare these proceedings with extradition law and that the case of *Norris v Government of the United States of America [2008] AC 920* indicated that it was wrong to consider conduct when considering a foreign conviction in Fitness to Practise proceedings. He the Tribunal's attention to paragraph 76 of *Norris* and said that this set out that the conduct test should be used:

> *'It is Mr Norris's central contention that in enacting section 137 Parliament deliberately eschewed the approach adopted in the 1989 Act and instead chose language mirroring the 1967 Act. The 1967 Act spoke of the act or omission constituting the offence, the 2003 Act of an offence constituted by the conduct. Both Acts, he submits, focus on that part of the conduct which constitutes the foreign offence, not the other parts which are extraneous to it but which may be alleged in documents supporting the extradition request: the court can have regard only to such conduct as would prove the essential ingredients of the foreign offence, nothing more. In short, Mr Norris contends for the offence test, not the conduct test.'*

150. Mr Shaw submitted that any inference that the Tribunal drew from the Information must pass the inevitability test as set out in paragraph 59 of the *Cleveland* case.

## The Legal Principles

151. The parties accepted that there was no legal advice to be provided. Each party had presented their interpretation of the statutory provision and it was a matter for the Tribunal to decide which construction was preferred.

## The Tribunal's decision

152. The Tribunal considered carefully the submissions made by the parties. The Tribunal examined the provisions of the Extradition Act 2003, to which they had been referred by

the Ms Beattie. The Tribunal considered the statutory intention of the Extradition Act which directs a wide, conduct approach to the comparison between foreign and English and Welsh offences.

153. The Tribunal gave particular consideration to *Norris* and *Cleveland* and the articulation by Lord Steyn in *In re Ismail [1999] AC 320*, as quoted in *Norris* that *'"a broad and generous construction" should be given to extradition statutes "intended to serve the purpose of bringing to justice those accused of serious crimes. There is a transnational interest in the achievement of this aim"'* The Extradition Act 2003 adopts a wider construction to dual criminality focusing on conduct rather than the specific elements of the offence. This wider construction obviates the need to investigate the legal ingredients of the foreign offence and the necessity for expert evidence from foreign jurisdictions.

154. The Tribunal disregarded Mr Shaw's assertion that the Extradition Act propounds a conduct approach because it applies only to future proceedings and thereby presents an imponderable prediction which was distinct from section 35(c)(2)(c), which refers to a conviction, a fixed point with no prediction required, as the Extradition Act dual criminality and conduct approach applies equally to cases in which the requested person is already convicted.

155. The Tribunal accepted Mr Shaw's argument that the statutory language was distinct and intentional. The Tribunal accepted his natural and ordinary language approach and the emphasis on offence, not conduct in section 35(c)(2)(c). The Tribunal accepted that the purposes of the Acts were of a different nature, the Extradition Act to ensure criminal justice outcomes were achieved across borders and the Medical Act to protect the public by ensuring that doctors are fit to practice. The Tribunal also accepted that the GMC had been required to stipulate the constituted offences following a preliminary hearing.

156. Accordingly the Tribunal endorsed a technical, narrow approach to determining the elements of the offence in this case.

ANNEX C: Application of no case to answer under Rule 17(2)(g) – 29/06/2023

157. At the conclusion of the GMC's case, Mr Shaw, KC, on behalf of Dr Baxter, made an application pursuant to Rule 17(2)(g) of the General Medical Council (Fitness to Practise Rules) 2004 as amended ('the Rules'), which states:

*'the practitioner may make submissions as to whether sufficient evidence has been adduced to find some or all of the facts proved and whether the hearing should proceed no further as a result, and the Medical Practitioners Tribunal shall consider any such submissions and announce its decision as to whether they should be upheld.'*

158. This application related to the following paragraphs of the Allegation:

> *4. You failed to notify the General Medical Council without delay that you had formally admitted to the criminal offence outlined at paragraph 1.*
>
> *The offence outlined at a paragraph 1, if committed in England and Wales, would constitute a criminal offence (see Annex A).*

## Submissions

Submissions on behalf of Dr Baxter

159. Mr Shaw submitted that, on a proper understanding of US process, there was no delay in notifying the GMC as Dr Baxter's formal admission, made as part of the Plea Agreement in August 2020, was not binding/irrevocable until the date of his sentence on 17 December 2020. He submitted that the GMC accepted that Dr Baxter made contact by way of self-referral on 6 January 2021 and that the self-referral form itself quickly followed, on 11 January 2021. He submitted that this period of 20 days over the Christmas and New Year holidays could not possibly amount to '*delay*', let alone undue delay.

160. Mr Shaw submitted that it would be wrong for the GMC to rely on any earlier starting point and that to use the language of the Allegation, Dr Baxter *'formally admitted'* the US offence on 17 December 2020. Until that date the US court could have rejected the Plea Agreement/admissions of Dr Baxter. He submitted that, on this basis, it would be inappropriate to consider the date of the Plea Agreement and the plea hearing as the closest US equivalent to the date of a charge under UK criminal procedure.

161. Mr Shaw submitted that, even if Dr Baxter had referred himself to the GMC in September 2020, it was very unlikely that any fitness to practise steps would have been taken before January 2021. He submitted that the GMC would have, perfectly reasonably, asked Dr Baxter to keep it informed of US developments, and would not

have taken any real investigative steps until he had been convicted. He submitted that no time would have been saved and Dr Baxter's self-referral in January 2021 rather than September 2020 made no practical difference.

162. Moreover, Mr Shaw submitted that the evidence of Dr Baxter's Responsible Officer confirmed that he had never sought to conceal the existence or evolution of the US investigation/proceedings. He had always fully engaged with his annual appraisals and kept his Responsible Officer promptly and properly informed on these matters. He submitted that this transparency was itself inconsistent with the allegation of delay or, at the very least, showed that it was an innocent/inadvertent oversight.

163. Mr Shaw submitted that, taking the case law of *Galbraith* into account, if the Tribunal took the facts of the case at their highest and determined that there was a four and a half month interval before Dr Baxter referred the matters to the GMC, the Tribunal should still determine that the GMC case was not made out. He submitted that even if it was such an interval, this would not amount to *'delay'* in the circumstances in this case. He submitted that there is no definition of '*delay'* in GMP or elsewhere and that the interpretation of this wording depends upon the particular circumstances. He submitted that in the circumstances of this case as set out above, including that there was no attempt to conceal these matters, there was not any undue delay and the Tribunal should grant the application.

164. Mr Shaw adopted the arguments he had made in response to the GMC opening on paragraph 4. He submitted that there were too many differences in the elements of the offence under the 2008 Business Regulations to allow for a finding of equivalence. Mr Shaw said that the Tribunal's key task was to consider whether there had been a '*conviction* [outside the UK] for an *offence* which, if *committed* in England and Wales, would constitute a *criminal offence*.' As a matter of natural and ordinary language, those words demand a simple comparison between the wording/elements of the *offences.*

165. He said that when the offences are compared various differences are obvious. The US offence is a *status* offence, one of strict liability involving proof of only two elements: misbranding and corporate managerial status. The offence in regulation 6 requires proof (to the criminal standard) of *additional* elements especially, but not only, proof of the accused's state of mind. For example, unlike the England and Wales offence, the US prosecutor need not prove any *'likely effect on traders' economic behaviour'* or that the misbranding *'injured or was likely to injure a competitor.'*

166. Mr Shaw asserted that regulation 8 requires proof that the corporation itself committed the *same* offence. The offence to which Indivior pleaded guilty was not the same offence to which Dr Baxter pleaded guilty. Further, that offence had to be committed with the consent, connivance or neglect of the company officer. The US offence to which Dr Baxter pleaded guilty requires no such mental element. The RCO offence is genuinely strict liability and dependent on status alone.

Submissions on behalf of the GMC

167. Ms Beattie, KC, on behalf of the GMC, submitted that there was sufficient evidence that a properly directed Tribunal could find this paragraph of the Allegation proved and that the application should be refused.

168. Ms Beattie submitted that in order to grant the application the Tribunal would need to determine that there was no evidence that Dr Baxter had *'formally admitted to the criminal offence'* in August 2020 and there had been no delay in informing the GMC. She submitted this was not the case. On the documentary evidence, including the Plea Agreement and defence case summary provided to the GMC, and considering the factual timescales of events, a properly directed Tribunal could, taking the evidence at its highest, find this paragraph of the Allegation proved.

169. Ms Beattie submitted that, following the Tribunal's decision in Annex B, it is not for the Tribunal to decide if there is an identical offence in England and Wales, it is whether the convicted offence has an equivalent offence. That is whether the acts or omissions admitted by Dr Baxter in the US could be a criminal offence in England and Wales.

170. Ms Beattie, taking into account the effect of the decision in Annex B, focused her submissions on the 2008 Regulations. She asserted that the Tribunal are entitled to draw any inferences that appear proper from that material, including any required mens rea and infer the 'additional elements' of the offence identified by Mr Shaw. She referred to the broad definition of advertising in Regulation 3(2) which includes any form of representation made in connection with a trade, business or profession to promote the supply or transfer of a product. She asserted that this must be equivalent to the broad category of labelling in 21 U.S.C section 352(a) which includes brochures, booklets, letters, literature and exhibits. She said that introducing into interstate commerce was

equivalent to being likely to affect a trader's economic behaviour or injure or likely to injure a competitor as required by the England and Wales Regulations.

171. Ms Beattie said that the purpose of the misleading data provided to MassHealth can only have been for commercial purposes i.e., selling Suboxone Film. She referred the Tribunal to the evidence in the Information, which Dr Baxter had admitted to:

*'...Baxter, as a responsible Indivior executive, failed to prevent and promptly correct the distribution of the false and misleading unintended paediatric exposure data and marketing claims to MassHealth'.*

172. Ms Beattie asserted that *'failed to prevent and promptly correct'* amounts to neglect to do something. In those circumstances the test for *'neglect'* is incorporated both within the US test in relation to establishing liability and within the 2008 Regulations. It is in essence the same.

173. Ms Beattie answered Mr Shaw's assertion that the Regulation 8 requirements were not met because the body corporate had not been convicted by the same offence. She explained that the Information that Indivior agreed was, in all relevant and material respects, exactly the same as that forming the Information to which Dr Baxter pleaded guilty.

174. Ms Beattie submitted that the views of the Case Examiners were not relevant to the Tribunal as they are formed at an early stage when not all the evidence is available. Decisions of the Case Examiners should not therefore influence the Tribunal's determination.

175. She submitted that there was sufficient overlap in the US conviction and the 2008 Regulations to find that it would constitute a criminal offence in England and Wales.

## The Relevant Legal Principles

176. The Tribunal accepted the advice of the LQC in determining the application. The LQC referred the Tribunal to Rule 17(2)(g) of the Rules, as set out above.

177. The Tribunal reminded itself that at this stage of the proceedings it was not considering whether it would or would not find each paragraph proved but whether, taking the GMC evidence at its highest, sufficient evidence had been adduced for there to be a case for Dr Baxter to answer. The Tribunal bore in mind that if it found that there was sufficient evidence for the hearing to proceed on a particular paragraph, it would have to decide, in the light of all the evidence before it at the end of the fact-finding stage, whether that paragraph had in fact been found proved or not. In considering whether sufficient evidence had been adduced to find some or all of the facts proved, the test to be applied by the Tribunal is as set out in *R v Galbraith [1981] 2 All ER 1060* which states, with adapted wording for the Tribunal:

*'How then should the Tribunal approach a submission of 'no case'?*

*(1) If there is no evidence that the fact alleged has been committed by the medical practitioner, there is no difficulty. The Tribunal will of course stop the case.*

*(2) The difficulty arises where there is some evidence, but it is of a tenuous character, for example, because of inherent weakness or vagueness or because it is inconsistent with other evidence.*

*(a) Where the Tribunal comes to the conclusion that the GMC evidence, taken at its highest, is such that a properly directed Tribunal could not properly find the fact proved upon that evidence, it is the Tribunal's duty, upon a submission being made, to stop the case in relation to that alleged fact.*

(b) *Where however the GMC evidence is such that its strength or weakness depends on the view to be taken of a witness' reliability, or other matters which are generally speaking within the province of the Tribunal, and where on one possible view of the facts there is evidence upon which a Tribunal could properly find the fact proved, then the Tribunal should not make a direction of no case to answer.'*

178. The Tribunal adopted a plain English approach to the wording of paragraph 3 of the Allegation in reaching its determination.

## The Tribunal's Determination

179. In considering whether there was no case to answer, the Tribunal had regard to the detailed submissions made by both parties and the totality of the evidence before it.

180. The Tribunal particularly bore in mind the following evidence:

- The Plea agreement, dated 28 August 2020 (where Dr Baxter states *'I am pleading guilty as described above* (i.e., to the charge) *because I am in fact guilty'*;
- The Information, dated 29 August 2020;
- The sentencing judgment, dated 17 December 2020;
- Dr Baxter's GMC self-referral statement dated 11 January 2021;
- Dr Baxter's witness statement dated 18 August 2022;
- Case summary prepared by Dr Baxter's legal team.

181. The Tribunal adopted a plain English, natural and ordinary meaning construction of paragraph 75 of GMP *'You must tell us without delay'* as meaning '*right away, immediately'* and '*as soon as reasonable/reasonably practical'*. Paragraph 75 states:

> *'75 You must tell us without delay if, anywhere in the world:*
>
> *a you have accepted a caution from the police or been criticised by an official inquiry*
> *b you have been charged with or found guilty of a criminal offence*
> *c another professional body has made a finding against your registration as a result of fitness to practise procedures.'*

182. The Tribunal considered Ms Beattie's submission that Dr Baxter had pleaded to a criminal offence in the hearing dated 31 August 2020, so at that point was aware that he had been charged. It also bore in mind the submission made on behalf of Dr Baxter that even if a Tribunal were to find that Dr Baxter had been charged and formally admitted to the charges in August, this would still not constitute a failure to notify without delay.

183. The Tribunal concluded that there was documentary evidence which could, on one view, support the GMC's case that Dr Baxter had formally admitted to these charges in August 2020 and also that there was a subsequent delay in his notifying the GMC.

184. The Tribunal considered the submissions and skeleton arguments and had sight of the US and England and Wales Regulations. The Tribunal carefully considered, compared and contrasted the US legislation and the Regulations.

185. Having reminded itself of the principles of the test applied as the target in *Galbraith*, adapted subsequently for use in regulatory proceedings, the Tribunal determined that the evidence and known facts were such that a properly directed tribunal could find the elements of paragraph 3 of the Allegation proved.

186. After analysing the relevant US legislation and England and Wales Regulations the Tribunal determined that there was an equivalent offence.

187. The Tribunal determined that a Tribunal considering the evidence and taking it at its highest, could find proved that Dr Baxter *'failed to notify the General Medical Council without delay that [he] had formally admitted the criminal offence outlined at paragraph 1 [of the Allegation]'* and could find that the criminal offence if committed in England and Wales would constitute a criminal offence. The Tribunal refused Mr Shaw's application made under Rule 17(2)(g) of the Rules.

SCHEDULES:

*ANNEX A*

1. *The relevant offences in England and Wales are:*

   i. *Pursuant to the Business Protection from Misleading Marketing Regulations 2008; [Regulation 2, 2(1), 3, 6, 8(1) and 8(2)]; and/or alternatively*

   ii. *Pursuant to the Human Medicines Regulations 2012 [Regulation 96, 338(1) and Part 13].*

2. *Your conduct, acts and/or omissions would constitute one or both of the criminal offences set out above.*