IN THE ROYAL COURTS OF JUSTICE QUEEN'S BENCH DIVISION ADMINISTRATIVE COURT



BETWEEN:-

THE PROFESSIONAL STANDARDS AUTHORITY FOR HEALTH AND SOCIAL CARE

Appellant

-and-

(1) THE GENERAL PHARMACEUTICAL COUNCIL

(2) MRS MOONIRA RIAZ HINGLOTWALA

Respondents

DRAFT ORDER

UPON the Appellant and the First Respondent having agreed to the terms of this Order, in particular that it is just and convenient for the Court to make the Order set out below

AND UPON the Second Respondent being a Pharmacist entered on the Register established and maintained by the First Respondent

And UPON neither party being a child or protected party and the appeal not being an appeal from a decision of the Court of Protection

AND UPON a panel of the Fitness to Practise Committee of the First Respondent ("the Committee") having found on 6 April 2023 that the Second Respondent had "no case to answer" in respect of an allegation, set out in Schedule 1 to this Order, that her fitness to practise was impaired ("the decision")

AND UPON the Appellant having lodged an appeal on 31 May 2023 against the decision pursuant to Section 29 of the National Health Service Reform and Healthcare Professions Act 2002

AND UPON the First Respondent conceding that the decision was not sufficient for the protection of the public within the meaning of Section 29 of the National Health Service Reform and Healthcare Professions Act 2002

AND UPON the Second Respondent having indicated that they are neutral in relation to the appeal.

BY CONSENT IT IS ORDERED THAT:

- 1. The Appellant's appeal is allowed on the basis of the grounds and reasons set out in Schedule 2 to this Order
- 2. The decision of the Committee on 6 April 2023 finding no case to answer is quashed, and the allegation set out in Schedule 1 to this Order, subject to any amendment being made by the First Respondent, is remitted to be heard by a freshly constituted panel of the First Respondent's Fitness to Practise Committee. Any amendments to the allegation are to be served on the Second Respondent at least 28 days before any remitted hearing
- 3. The First Respondent shall pay 50% of the Appellant's reasonable costs incurred up to the date of 21 June 2023 and incurred in the drafting and agreement of this Order. The remainder of the Appellant's costs are to be paid by the Second Respondent

Dated this 15th day of January 2024

Name: Name: Helen Fleck Name Moonira Hingiotwala

Brown Jacobson LLP GPhC 2nd Respondent

On behalf of Appellant 1st Respondent

SCHEDULE 1: Particulars of allegation

You, a registered Pharmacist,

- 1. You are the owner and superintendent Pharmacist ("SI") for Tebi Health Limited, trading as Riaz Pharmacy ("the Pharmacy"), 112 Randal Street, Blackburn, BB1 7LG.
- 2. Between approximately June 2018 to on or around the beginning of August 2020, in your capacity as the SI, you oversaw purchases from wholesalers and/or caused and/or allowed sales to customers of excessive volumes of codeine linctus, without ensuring the Pharmacy had adequate controls in place to:
 - 2.1. monitor such purchases;
 - 2.2. monitor sales to customers;
 - 2.3. identify sales to repeat customers;
 - 2.4. minimise the potential for patient misuse or addiction.
- 3. Between approximately June 2018 to on or around the beginning of August 2020 and September 2020, you allowed sales of codeine linctus to patients:
 - 3.1 Without assurance that there was a legitimate medical need for it and/or the medication was a legitimate treatment option
 - 3.2 In circumstances where you knew and/or ought to have known that there was a risk of the

codeine linctus patient being misused or abused by the patient

And by reason of the matters set out above, your fitness to practise is impaired by reason of your misconduct.

SCHEDULE 2:

The appeal in this matter is conceded on the following basis:

Mrs Moonira Riaz Hinglotwala, the Second Respondent ("the Registrant") is a pharmacist. This is an appeal under section 29 of the National Health Service Reform and Health Care Professions Act 2002 ("the 2002 Act") against a decision of the General Pharmaceutical Council's ("GPhC") Fitness to Practise Committee ("the Committee"), made on 6 April 2023, in respect of the joined cases of Riaz Hinglotwala (Reg No. 2047339) ("Mr. Hinglotwala") and Moonira Riaz Hinglotwala (Reg no. 2054349) ("Mrs Hinglotwala") (together known as "the Registrants").

The Particulars of Misconduct faced by both registrants involved failures to out in place adequate governance mechanisms or to adequately oversee and monitor the purchase and sale of codeine linctus in circumstances where there was no legitimate need for it and where they knew or ought to have known that it was likely to have been abused or misused. Codeine linctus is susceptible to abuse / misuse and can be mixed with other substances to form recreational drugs such as the drink known as "purple drank" or "lean".

Following submissions made on behalf of both registrants, the Committee decided that there was no case for the registrants to answer on the facts, on the basis that it did not hear any evidence to show that there was a statutory limit or guidance or best practice to establish that sales of codeine above a particular level would be excessive, and found that the there was only one piece of evidence before it that indicated that sales of codeine linctus did not meet the licence conditions for the product. Further the Committee found that there was no 'duty' to do what Particulars of Misconduct 2.1, 2.2 or 2.3 stated should be done as the Committee found that the relevant standards (i.e. GPhC Standards) were not put before it. The Committee found no evidence that sales had occurred without assurance.

The Appellant and First Respondent agree that this decision was wrong and insufficient to protect the public in that:

It was a serious procedural irregularity for the Committee to have

found that (a) it had not been referred to, and (b) it could not refer to the relevant GPhC standards in considering misconduct. The relevant standards were before the Committee in the First Respondent's skeleton argument. In any event, the standards are publicly available documents with which all pharmacists are expected to be familiar and abide by and the Committee is required to consider the extent to which the registrant had breached the Standards as published by the GPhC under Article 48(1), the Pharmacy Order 2010 There is no need for such documents to be exhibited or produced in order

for Committee's of the First Respondent to consider their application. Had the Committee considered the GPhC's objectives and the relevant Standards the evidence before the Committee could have established serious misconduct requiring imposition of a sanction in the public interest.

Ground 2: It was a serious procedural irregularity for the Committee to have found that it had to exclude the opinion / conclusion evidence of the GPhC Inspector. To exclude opinion evidence from GPhC's Inspectors in this case, and in general,

Ground 1:

places the public at potential risk of harm and undermines confidence in the profession and the system of regulation. The Committee erred in finding that:

- a. To have considered the opinion evidence of the Inspector would have been a substitute for making its own decision on the issue before it the Committee would still have been required, upon admission of any such evidence, to have reached its own determination.
- The decision In Rogers v Hoyle was authority for the exclusion b. of the Inspector's opinion evidence. The finding in the case was that the AAIB2 opinion report was admissible, on the basis that it is proper for a judge to have regard to a person's opinion who is better placed than the judge to form that opinion. The Inspector was present at the pharmacy at the time of its inspection, as well as being a qualified Inspector, and therefore the correct application of the decision in Rogers v Hoyle should have led to a finding that her opinion evidence was admissible. The Inspector represented a body established by statute and charged with the responsibility for the investigation of pharmacies, and therefore her findings were informed (whether explicitly or not) by first-hand experience, knowledge gained from past investigations as well as the general knowledge of pharmacies held by Inspectors. That knowledge and experience give her findings a special value and therefore it should have been admitted into evidence.

Ground 3: The Committee erred by focussing exclusively on issues concerning the GPhC Inspector's evidence in relation to quantity, and in failing to have any, or adequate regard to other relevant evidence, including whether controls were in place, before it in relation to an 'excess' of codeine linetus being sold. The failure to assess this evidence or take proactive steps to secure further relevant evidence places the public at potential risk of harm and undermines confidence in the profession and the system of regulation.

The Committee failed to have any or sufficient regard to the Witness Evidence from the GPhC's Inspections Operations Manager which set out the background to the concerns about the issues of large quantities of Codeine Linctus being ordered. Indeed, the content of the evidence was not addressed at all in the Committee's reasons. The Committee also failed to consider the evidence from the MHRA showing the amount of Codeine linctus purchased and the admissions from the registrants that as many as 1-2 bottles per day were sold.

Further, the Committee failed to consider that the word "excessive" was used in the context of the lack of 'adequate controls'; and that there was significant evidence showing that there was evidence of such lack of controls including: the opinion evidence of the Inspector, Standard operating procedures which were last reviewed in 2016 and the lack of any records showing codeine being prescribed or dispensed.

The Committee further erred in holding that $Professional\ Standards\ Authority\ v\ (1)\ Nursing\ and\ Midwifery\ Council\ (2)\ Jozi\ [2015]\ EWHC\ 764\ (Admin)\ -$ concerning the duty on a regulatory panel to be proactive in ensuring that relevant evidence is before it - did not apply to the circumstances of this case. Examples of other evidence required for the protection of the public that the Committee could have taken into account, or taken proactive steps to adjourn to obtain further details on, included what checks: had been made in relation to the supply of codeine linctus; were in place to govern frequency of orders; were in place to check with the patient's regular doctor; were in place to ensure a clear record of the reason for supply if there was no regular doctor.

Ground 4:

The Committee erred in failing to amend the charges as it was entitled to do under Rule 41, or part of the charge, applying Gangar v GMC [2003] 4 WLUK 231, or remitting the case back to the prosecuting authority to rewrite the charges. The Committee misdirected itself by taking the view that it was not entitled to amend the charges, to replace the term 'excessive' in Particular 2 with another term relating to volume. The charges could have been amended to consider the absolute, not relative volume of sales. As a consequence of its decision, the Committee made a finding of "no case to answer" which places the public at potential risk of harm. Further the Committee could have adjourned to request that the charges be amended in the public interest, or alternatively to obtain independent statistical evidence about whether the quantities sold were 'excessive'. As a consequence of its decision, the Committee made a finding of "no case to answer" which places the public at potential risk of harm and undermines confidence in the profession and the system of regulation.