Ongoing off-label prescribing of high-risk medications sees GP's registration suspended for two years

Key messages from the case

Off-label prescribing may be clinically appropriate but particular care is needed. If considering off-label or unconventional uses of medications, doctors need to ensure their prescribing choice meets the required standards of professional practice.

Details of the decision

Dr T was a GP with nearly 40 years' experience when his prescribing came to the attention of the Medical Board. Concerns were raised over his prescribing or administering medications including peptides (GRHP), steroids (testosterone and DHEA), aromatase inhibitors (Anastrozole), thyroxine medications (T3 & T4) and metformin to 20 patients over the course of 8 years.

Informed consent

The Medical Board alleged Dr T had prescribed unapproved or off-label medications without advising patients of the experimental nature of the prescribing and therefore failed to obtain effective informed consent.

Standard of care

The Board also claimed he had put patients at risk by:

- prescribing based on his own 'unconventional understanding' with insufficient evidence of appropriateness or clinical efficacy
- failing to adequately examine the patients or assess the appropriateness of his prescribing
- prescribing medications to patients for whom they were contraindicated (for example prescribing metformin to a patient in renal failure)
- failing to appropriately monitor the dosages, effectiveness or potential adverse effects of the treatments
- failing to address symptoms or consider more appropriate treatments when patients experienced possible adverse effects of the medications.

Expert evidence indicated Dr T's treatments were largely experimental and not supported by evidence. The risks and benefits were unknown.

Dr T initially disputed that his prescribing was below the standard expected but over time, and after receipt of the Board's expert evidence, changed that position. By the time of the hearing, Dr T indicated that his registration had lapsed and he was relinquishing his practice.

The tribunal concluded Dr T's prescribing amounted to a serious departure from the standard of care expected. Dr T ultimately accepted his behaviour constituted professional misconduct.

Medical records

The Medical Board also alleged Dr T had breached his professional obligations to keep appropriate records of his prescribing or monitoring of the patients. He had failed to:

- record his reasons for prescribing the medication or substantiating that the medications were clinically indicated
- record his assessment of the patients
- document his explanation to the patients or obtain their written informed consent to unconventional or experimental treatments
- outline any ongoing treatment and monitoring plan
- document any evidence indicating that the treatments were likely to be effective.

Dr T accepted the expert evidence that his record-keeping was inadequate.

The tribunal noted that the inadequate record-keeping and failure to obtain and document informed consent was a significant aggravating factor where patients were being prescribed unproven and potentially harmful medications.

Outcome

As well as the risk of harm to the patients, the tribunal noted the broader public interest concern about the lucrative market for medications for body-building and similar non-therapeutic purposes. It noted with approval previous determinations that sanctions needed to be sufficiently severe to provide a disincentive for practitioners to service this market.

The tribunal found Dr T expressed no insight regarding his behaviour and that he could not currently be trusted to practise safely.

Dr T was reprimanded and disqualified for two years.

Key lessons

- always follow appropriate prescribing practices, including taking an adequate history, examining the patient and assessing the appropriateness of the medication
- ensure that you can support your prescribing with high-quality evidence
- make sure you are aware of and follow any applicable guidelines
- explain that the prescription is off-label and what this means in termsof risks or limitations in the evidence
- obtain the patient's written informed consent to an off-label use where possible
- always plan appropriate monitoring and follow-up
- if other healthcare providers are involved in the patient's care, communicate with them about the prescribing and your clinical reasoning
- clearly document your prescribing decision, consent discussion and ongoing monitoring.

References and further reading

Avant eLearning - Prescribing principles: Part one: General prescribing issues

Avant article - Prescribing off-label: factors to consider

AJGP article - RACGP – Off label medicine use

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