

Practice Alert

Steroids and hormone therapies – Off label use or misuse/abuse?

Pharmacists are expected to have a contemporary knowledge of the drugs that are subject to abuse or misuse, both generally and in their own localities. Steroids and hormone therapies are one of many groups of medications that are the subject of abuse/misuse.

Many individuals source anabolic steroids illicitly from coaches, friends, teammates, gym employees, relatives and even clinicians or health workers (doctors, pharmacists, and veterinarians).

While the potential for misuse/abuse of injectable steroids (such as Sustanon, Primoteston and Reandron) is more obvious, other hormone therapies susceptible to abuse/misuse include:

- Tamoxifen and Arimidex/Anastrozole (to prevent gynaemastia associated with the use of anabolic steroids)
- Pregnyl/human chronic gonadotrophin (to stimulate the testes when withdrawing from exogenous androgens) and
- Clomid/clomifene (to raise testosterone levels or stimulate endogenous testosterone after anabolic steroid use).

Non-medical use of androgenic anabolic steroids is not just limited to body builders, with research suggesting that some individuals report they first commenced using anabolic steroids to boost their self-esteem, enhance their appearance or body image, gain more muscles or strength, as well as improving sport or work performance.

Articles referring to off label use of some of the above medications to treat male hypogonadism have been published but the significance of low testosterone in men is controversial. Pharmacists should be vigilant when requested to dispense steroids and hormone therapies. Requests for drugs which are susceptible to

misuse/abuse should be treated circumspectly because of manipulative behaviour by individuals seeking these drugs for inappropriate purposes.

Consider

- Could the prescription be fraudulent?
- Information in the Australian Medicines Handbook, electronic Therapeutic Guidelines and eMIMS
- PBS requirements (for example, must the prescriber be a specialist? Is an authority required? Is the PBS rebate only available when the medication is prescribed for certain conditions?)
- Other regulatory requirements for supply of medications under the PBS (for example Regulation 49).

Critique

- Does the prescription accord with recognised therapeutic standards?
- Has the medication been prescribed in accordance with accepted therapeutic indications?
- Does the patient's dispensing history indicate misuse/abuse (for example, does the frequency of prescriptions fall outside a normal therapeutic range/does?)

Clarify – with the prescriber and/or patient

- Is there a genuine therapeutic need? This must be established by careful questioning. This is essential to determine and confirm the therapeutic indications for the prescribed medications to ensure that the prescription is appropriate and dispensing is safe.
- Pharmacists should consider the patient's and prescriber's explanation(s) and exercise independent professional judgment before dispensing the prescription, even if this appears disrespectful to another practitioner.¹

¹ *Pharmacy Board of Australia v Smith* [2012] QCAT 186

Counselling

Counselling must be offered even though many patients may not be receptive to this. Pharmacists should ensure that more private areas are available if sensitive issues (such as infertility) need to be discussed. If a patient cannot or will not articulate the reason they have been prescribed the medication this may serve as a prompt for the pharmacist to review the appropriateness of the prescription.

Record and report

Make a note of the conversation with the prescriber and/or patient. This will assist:

- colleagues
- with recall in event of an AHPRA notification or other investigation (for example, criminal or coronial) and
- to track trends/patterns in a patient's prescriptions or the dispensing pattern of a prescriber.

Consider communicating evidence of any developing trend in the use of drugs of abuse/misuse to authorities, colleagues and professional bodies.

Consequences

Keeping abreast of the Australian professional literature, media and engagement with colleagues is strongly recommended. Where prescriptions are presented with unusual and/or high doses of drugs or if the drug is known to be subject of abuse, pharmacists have professional obligations to ensure the appropriateness of the prescription, the welfare of the patient and to maintain the quality use of medicines².

Failure to do so may constitute professional misconduct or unprofessional conduct and result in:

- cancellation or suspension of a practitioner's registration and/or conditions being placed on their registration (such as a requirement to undertake education, mentoring and or supervision) and
- adverse costs orders (in the event of referral to State Administrative Tribunals) and
- the potential for criminal charges³.

² *Pharmacy Board of Australia v Swan* [2016] QCAT 475

³ *Pharmacy Board of Victoria v Dangigelis* (Occupational and Business Regulation) [2010] VCAT 1276

Examples

The following examples provide cogent reminders of the types of circumstances where the Pharmacy Board of Australia is likely to make determinations of unprofessional conduct:

- prescriptions for anastrozole which is usually prescribed to treat hormone receptor positive breast cancer in post-menopausal women were dispensed to males without making sufficient inquiries with the patient and/or prescriber
- medications have been dispensed contrary to the accepted clinical and therapeutic indications when the only explanation the patient provided to the pharmacist was limited to '*my hormone therapy*'
- Primoteston which was not prescribed by or in consultation with a specialist was dispensed without confirming whether the patient had an established pituitary or testicular disorder
- prescriptions for Armidex, Saxenda, Sustanon and Primoteston were dispensed to a single patient over a period of three weeks and
- Clomid, which is usually prescribed for anovulatory infertility was prescribed/dispensed to male patients under a PBS item code when the PBS benefit is restricted for patients undergoing in-vitro fertilisation. It should be noted that occasionally this medicine may be prescribed for men for fertility purposes, however this off-label prescribing should not be a PBS item and would be prescribed or recommended only under guidance of a fertility specialist.

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