Penalties for prescribing and dispensing isotretinoin without authorisation

Issue 30, August 2015

Target audience: General practitioners and pharmacists.

Purpose

To summarise the current Health (Drugs and Poisons) Regulation 1996 (HDPR) requirements for prescribing of isotretinoin by doctors and dispensing of isotretinoin prescriptions by pharmacists and penalties for prescribing and dispensing of isotretinoin without authorisation.

Background

The National Poisons Standard (Number 8, July 2015) includes isotretinoin in Schedule 4 – Prescription Only Medicine and notes that isotretinoin requires additional controls as listed in Appendix D of the National Poisons Standard. Medicines may be included in Appendix D for example, where there are specific health risks that may be mitigated by restricting availability through specialist medical practitioners. Under Appendix D, isotretinoin is available only on the prescription or order of a specialist physician or a dermatologist, AND, where the patient is a woman of child-bearing age, the prescriber must:

1. ensure that the possibility of pregnancy has been excluded prior to commencement of treatment; and
2. advise the patient to avoid becoming pregnant during or for a period of 1 month after completion of treatment.

In Queensland, these conditions are reflected in the HDPR. Medicines in Appendix D are known as regulated restricted drugs in the HDPR.

Who is authorised to prescribe isotretinoin?

Under the HDPR section 186, dermatologists and specialist physicians (and their registrars working directly under the supervision of these specialists) are authorised to prescribe isotretinoin. Other doctors may seek approval from the Department of Health to prescribe isotretinoin for a patient where the patient:

1. has recently been assessed by a dermatologist or specialist physician as having a therapeutic need for isotretinoin; and
2. lives at a remote place where the patient cannot access the services of the dermatologist or specialist physician in person.

Where these conditions (section 186(2)) are met, a general practitioner may apply for an approval to prescribe isotretinoin by completing the application form for regulated restricted (Schedule 4) medicines on this webpage https://www.health.qld.gov.au/system-governance/licences/medicines-poisons/approvals-authorities/default.asp.

Section 190 requires the medical practitioner who is authorised under section 186 to write the word ‘Approved’ on the prescription in addition to the other requirements for a prescription.
Medical practitioner offences and penalties

A medical practitioner who prescribes isotretinoin outside the circumstances allowed under section 186 of the HDPR is committing an offence with a maximum penalty of 80 penalty units, equivalent to $9,424 as at 1 July 2015\(^1\).

There is also a penalty (60 penalty units or $7,068) for not writing a prescription in the way that complies with section 190 e.g. failing to write the word ‘Approved’ on a prescription.

Pharmacist offences and penalties

There are a number of offences and penalties that apply to a pharmacist who dispenses a prescription for isotretinoin:

- from a medical practitioner who is not authorised to prescribe isotretinoin (maximum penalty of 80 penalty units, equivalent to $9,424)
- where the word ‘Approved’ does not appear on a prescription for isotretinoin or where the prescription does not comply with the other requirement of the HDPR section 190 or where the address of the prescriber is not in Queensland (maximum of 60 penalty units or $7,068 for each offence).

If a pharmacist is presented with a prescription written by a medical practitioner who is not authorised under HDPR section 186 or where the prescription does not comply with the requirements under section 190 (e.g. does not include the word ‘Approved’), then the pharmacist is required under section 193A to:

1. cancel the prescription by legibly and permanently indicating that the prescription is not to be dispensed and including the date and name or initials of the dispenser, and the name and address of the pharmacy, and
2. send the prescription to the Department of Health within 14 days of cancelling the prescription.

Failure to do so may attract a maximum penalty of 40 penalty units ($4,712). The pharmacist may fulfil this requirement by emailing a scanned image of the cancelled prescription to MRQ@health.qld.gov.au.

Recommendations

Medical practitioners and pharmacists should make themselves aware of the requirements and legal obligations related to prescribing and dispensing of isotretinoin as significant penalties may apply for non-compliance with the HDPR requirements.

Note that similar specialist prescriber requirements and offences apply to the prescribing and dispensing of other regulated restricted drugs such as clozapine, dinoprost and clomiphene (see HDPR sections 185 to 188B).

For more information please contact:

Medicines Regulation and Quality
Phone: 07 3708 5264
Fax: 07 3708 5431
Email: MRQ@health.qld.gov.au

\(^1\) The penalty unit value in Queensland is $117.80 (current from 1 July 2015) for offences by an individual.