Medication Safety Watch

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Health Quality & Safety Commission New Zealand
Kupu Taurangi Hauora o Aotearoa

Medication Safety Watch

A bulletin for all health professionals and health care managers working with medicines or patient safety.

Key messages

- Off-label use of medicines
- Transdermal patches alerts
- US medication safety best practices
- Incidents and cautions

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Medication alerts and safety signals

These alerts and safety signals provide information and actions about high-risk medicines and situations. They are issued to health care staff, managers and organisations. For more information, contact Beth Loe at beth.loe@hqsc.govt.nz.

UPCOMING: An oral metoprolol alert is in development.

Contribute to Medication Safety Watch

Are you or your organisation working on a new medication safety initiative? Has there been a medicine-related incident or error that you would like to warn others about? If so, contact Beth Loe at beth.loe@hqsc.govt.nz.

Unapproved use of an approved medicine (off-label use)

When a medicine is approved by a regulatory agency, it is approved for use for specific indications, specific age ranges, specific doses and specific routes. When a medicine is prescribed for a different indication, patient age range, dose or route it is considered to be unapproved or off-label use. Medsafe have produced guidance on the use of unapproved medicines and the unapproved use of medicines.[1]

Prescribing off-label is unavoidable and common, especially if the prescribing is for children, pregnant women, mental health or palliative care. Product information will not include information about off-label use and manufacturers are not allowed to promote any off-label use. However, common off-label use of medicines will often be included in reference sources.

Off-label prescribing occurs in both primary and secondary care, although much of the primary care off-label prescribing is likely to have been initiated in secondary care.

Off-label prescribing may be clinically appropriate but it brings with it a number of clinical, safety and ethical issues. Ideally the patient should know that the prescription is off-label, and why you are recommending the medicine. Making a note or recording that the patient 'consented' in their clinical record is good practice. The more uncommon the off-label use of the medicine is, the more important it is that the patient understands and accepts the rationale for use. This approach is no different to what should be done for the prescription of any medicine but the rationale for an off-label prescription might be more heavily scrutinised if a serious adverse reaction occurs. The conversation will also help to explain why the prescribed use does not match the information in the consumer medicine information leaflet.

Two countries have taken some specific action on off-label prescribing. The French government has introduced a new law and associated decree in the wake of a recent scandal involving off-label indication use of a medicine.[2] These provide a regulatory process for temporarily supervising the off-indication prescribing of medicines. The Council of Australian Therapeutic Advisory Groups (CATAG) has developed guiding principles for the quality use of off-label medicines.[3]

References

1. Medsafe. Use of Unapproved Medicines and Unapproved Use of Medicines. April 2013. URL: www.medsafe.govt.nz/profs/riss/unapp.asp (last accessed 3 Feb 2014).
2. Emmerich J, Dumarcet N, Lorence A. France's New Framework for Regulating Off-label Drug Use. NEJM 2012; 367 (14): 1279-81.
3. CATAG. Rethinking medicines decision-making in Australian Hospitals. Guiding principles for the quality use of off-label medicines. Nov 2013. URL: www.catag.org.au/wp-content/uploads/2012/08/OKA9963-CATAG-Rethinking-Medicines-Decision-Making-final1.pdf (last accessed 16 Jan 2014).

Inadvertent bolus potassium injection causes arrhythmias and death. Ensure concentrated potassium ampoules are removed from clinical areas or locked away rather than stored near other injections. Check this is still the case in your clinical area.

What's new?

Transdermal patches alerts

The Health Quality & Safety Commission issued two transdermal patches alerts in December 2013 targeted at secondary and aged residential care, to guide individual clinicians and organisational level actions. The alerts are available at *www.hqsc.govt.nz/our-programmes/medication-safety/publications-and-resources/publication/1303/*.

Open for better care *national patient safety campaign*

The *Open for better care* campaign being led by the Commission is now focused on reducing healthcare associated infections. The focus of the new topic is surgical site infections. For more information, go to *www.open.hqsc.govt.nz/infections*.

2014–15 US Medication Safety Best Practices for Hospitals

The Institute for Safe Medication Practices in the US has launched *2014–15 Targeted Medication Safety Best Practices for Hospitals*. The six recurring safety issues relate to:

- vincristine (and other vinca alkaloids)
- oral methotrexate
- weight in metric units
- oral liquids dispensed in oral syringes
- oral liquid dosing devices in metric measure only
- glacial acetic acid.

The document is written for US hospitals but is still applicable to the NZ setting. For more information, go to *www.ismp.org/Tools/BestPractices/default.asp*.

Kadcyla® and Herceptin®

Kadcyla® (trastuzumab emtansine) and Herceptin® (trastuzumab) are NOT the same product. Kadcyla® is an antibody drug conjugate and Herceptin® is an antibody. Both the trade and generic name should be used when prescribing Kadcyla® to reduce the risk of the wrong product being prepared and administered.

The Code of Rights applies to unapproved medicines

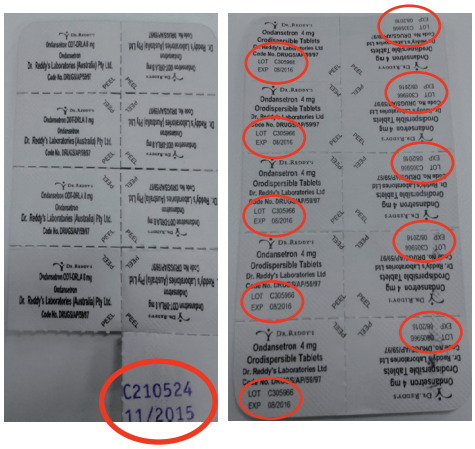
Medsafe has reminded all prescribers that when unapproved medicines are prescribed in New Zealand, the Code of Rights applies. The patient has the right to be given information about the medicine and informed consent should be obtained. For more information, go to *www.medsafe.govt.nz/profs/PUarticles.asp*.

Incidents and cautions

Changes to ondansetron foil package labelling

Dr Reddy's ondansetron tablets supplied in New Zealand have changed to the Australian packaging and labelling. The new font is harder to read and the lot number and expiry date are not printed on every blister. The labelling does meet the Medsafe labelling standard.

New packaging *Old packaging*



Be aware when dispensing individual foil wrapped tablets rather than a strip of 10 tablets that not all the tablets will have a lot number and expiry date on them. Once removed from an outer container, the labelling on the foil is hard to read.

Tenoxicam or tamoxifen?

There has been an increase in reports of tenoxicam being dispensed when tamoxifen was prescribed or vice versa. In all the reported cases, the label on the dispensed product has been correct but the product dispensed in the packet has been incorrect.

When doing a final dispensing check, ensure that the product in the container matches both the prescription and the label. For tablet blisters, this will mean opening the dispensed container.

Prescribing Rifinah® versus rifampicin

There have been two recent case reports when patients on combination isoniazid and rifampicin (Rifinah®) in hospital have been discharged on rifampicin alone. The risk of under-treatment and relapse of the tuberculosis are significant. There is also an increased chance of drug resistance developing.

1. How is isoniazid/rifampicin prescribed in inpatient areas in your organisation? If the answer is always generically, always as isoniazid/rifampicin, it is unlikely that this incident will occur.
2. If discharge prescriptions are prescribed electronically in your organisation, how is isoniazid/rifampicin shown in the drop-down box of the electronic system? If the answer is as isoniazid/rifampicin but inpatient prescribing is **not** done as isoniazid/rifampicin, then read on.
3. Not every prescriber will remember or consider that rifampicin/isoniazid or Rifinah® is isoniazid/rifampicin when writing a discharge prescription and will inadvertently choose rifampicin from the drop-down menu.

Review the prescribing of isoniazid/rifampicin (Rifinah®) in your organisation and how these products are displayed in the electronic discharge system.

Upcoming events

- The 19th annual International Forum on Quality and Safety in Healthcare, Paris, 8–11 April 2014. See *internationalforum.bmj.com/home* for more information.
- The 16th annual NPSF Patient Safety Congress, Orlando, Florida, 14–16 May 2014. See *npsfcongress.org* for more information.
- The eighth National Medicines Symposium, Medicines in health: Shaping our future, Brisbane, 21–23 May 2014. See *www.nps.org.au/about-us/what-we-do/campaigns-events/national-medicines-symposium* for more information.