

E-mail: gli@pharm.usyd.edu.au

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FURTHER READING

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Conflict of interest: none declared

Editorial note:

Traditional Chinese medicines account for only a small part of the use of complementary medicines in Australia. The problems of quality mentioned in this article are not confined to traditional Chinese medicines. This year's recall of complementary medicines made by Pan Pharmaceuticals shows that problems can arise even when products are manufactured in a modern factory.

Self-test questions

The following statements are either true or false (answers on page 151)

3. Traditional Chinese medicines may contain therapeutic and toxic components.
4. The method of preparation of a Chinese medicine may alter its pharmacological effects.

The quality and safety of traditional Chinese medicines

Comment by John McEwen and Fiona Cumming, Therapeutic Goods Administration

It may seem strange that the Therapeutic Goods Administration (TGA) regulates the safety and quality of Chinese **herbal products**, but does not scrutinise the **raw herbs** dispensed by Chinese medicine practitioners in Australia. The explanation lies in the extent of federal powers under the Australian Constitution. The *Therapeutic Goods Act 1989* relies on federal controls of importations, infectious diseases (quarantine), interstate trade and corporations (companies) to regulate the supply of medicines. This Act does not control the behaviour of individual practitioners – indeed those who are unincorporated and do not trade across state boundaries are outside the federal powers.

Chinese medicine herbal products on lawful sale in Australia must have an AUSTR or AUSTL number on the label. All Australian and overseas manufacturers of these products are required to authenticate their starting materials and testing of final products, and their performance is audited. This is a more efficient mechanism than a customs barrier scrutinising documentation for, and on occasions testing, every import of a raw herb or manufactured Chinese herbal medicine. It does mean, as the authors point out, that raw herbs can be imported and dispensed without any TGA control, but that situation is not absolute. A number of herbs with recognised toxicity are prohibited imports or are subject to State and Territory poisons controls, or both. These herbs should not be being dispensed by herbal practitioners.

Toxicity can occur through substitution of a toxic herb for a relatively non-toxic herb. There are 11 herbs which are vulnerable to substitution by the nephrotoxic, carcinogenic herb *Aristolochia*, because of confusion over their similar names and appearance. In the few instances where such substitution has occurred, in herbal products regulated as therapeutic goods, the TGA has required the affected products to be recalled. The TGA maintains a regular testing program for potential *Aristolochia* substitution, and has stringent pre-market regulatory controls in place to help ensure such substitution cannot occur. Although raw herbs are outside the TGA's powers, the TGA has worked with the Australian Customs Service and the States and Territories to put in place additional scrutiny of herbs which may be at risk of substitution with *Aristolochia*.

The possibility of deliberate adulteration is very real, as illustrated by the experience in Singapore and Malaysia in 1992, with a herbal product for weight loss. Slim 10 was manufactured in China and promoted heavily. Adverse reaction reports of serious illness and death led to the identification of not one, but two, adulterants – dried thyroid gland extract, presumably of animal origin, and a fenfluramine derivative. In recent years the TGA has not identified any instances of a conventional pharmaceutical being used to adulterate herbal products with AUSTR or AUSTL numbers. In contrast, there has been a small number of instances of clinically significant adulterants being found in herbal products unlawfully supplied in Australia or purchased overseas.

Even when not surreptitiously adulterated, there can be dangers.

On two occasions in the past four years, Chinese herbal products containing oxyphenisatin have been found in Australia. One of these products was labelled as containing diacetyldiphenolisatin – an alternative name. Oxyphenisatin has been included in an Australian list of substances ‘of such danger to health as to warrant prohibition of sale, supply or use’ because of its association with severe jaundice.¹

The TGA Laboratories Branch is skilled in analysing products for adulterants and all practitioners are urged to report suspected instances using the ADRAC blue card or the TGA web site.

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RADAR – Rational Assessment of Drugs And Research

RADAR is a new service from the National Prescribing Service (NPS). It will provide general practitioners, pharmacists and other health professionals involved in primary care with information about new medicines and changes to the Pharmaceutical Benefits Scheme (PBS).

RADAR will also provide commentaries on important research that may influence patient management. It will interpret clinical evidence and suggest where a new medicine might fit within the therapeutic armamentarium.

As RADAR will have access to information that has previously been unavailable, it will be able to provide the reasoning behind why a medicine has a particular PBS listing. If a

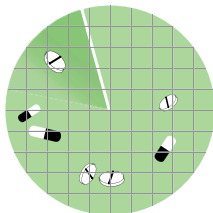
medicine requires an authority prescription, RADAR will describe the reasons why this restriction is required.

The publication of RADAR will coincide with the quarterly publication of the Schedule of Pharmaceutical Benefits – the ‘yellow book’ – so it will be available at the same time as new drugs. The NPS is also investigating incorporating RADAR into prescribing and dispensing software so that, in the future, access will be even easier.

Register for the service at www.npsradar.org.au and the NPS will deliver each edition of RADAR directly to your computer.

Look out for RADAR in the upcoming months. NPS RADAR – keep track of what’s out there.

Underneath the RADAR



The National Prescribing Service (NPS) produces RADAR (Rational Assessment of Drugs And Research) to inform people about changes to the Pharmaceutical Benefits Scheme. *Australian Prescriber* will be publishing some of the information underlying important changes, but a wider range of topics will appear in RADAR. The RADAR location is <http://www.npsradar.org.au>

On the RADAR: moxifloxacin

The quinolone antibiotic moxifloxacin has been listed on the Pharmaceutical Benefits Scheme (PBS), for the oral treatment of community-acquired pneumonia in adults and children over 12 years old who have immediate hypersensitivity to penicillin. An authority prescription will be required.

Underneath the RADAR

This new listing extends the number of patients who can be treated with moxifloxacin. The PBS already subsidises intravenous and oral moxifloxacin, but only for patients with severe community-acquired pneumonia who require admission to a high dependency unit or intensive care. The new listing means moxifloxacin can be prescribed in the community for patients who are hypersensitive to penicillin.

Comment

While moxifloxacin can now be used for less severe cases of pneumonia, it is not the drug of choice for most patients. The Therapeutic Guidelines: Antibiotic recommend that patients

treated outside hospital should receive oral amoxicillin with either roxithromycin or doxycycline. In patients who are allergic to penicillin, but do not have immediate hypersensitivity, cefuroxime can be substituted for amoxicillin. Moxifloxacin is therefore reserved for patients with immediate hypersensitivity to penicillin.¹ These patients will have a history of anaphylaxis, urticaria, bronchospasm or angioedema developing within 60 minutes of taking penicillin.

While quinolone antibiotics are currently effective in community-acquired pneumonia, bacterial resistance can develop quickly. It is therefore essential that moxifloxacin is only prescribed in the community when other antibiotics are unsuitable. In addition to a clear history of immediate hypersensitivity to penicillin, radiological confirmation of the pneumonia will be required before the drug can be supplied by the PBS.

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