

## Importation of unapproved prescription medicines

Medsafe is the regulatory authority responsible for administering the medicines legislation in New Zealand.

This letter details the requirements for authorising the importation of unapproved medicines for your patient. If you consider it appropriate to prescribe imported unapproved medicines for your patient please complete the second page of this letter and ensure it is submitted with the consignment.

**The medicine(s) may have been obtained from overseas and may have been ordered via the internet. As such, Medsafe has not evaluated the medicine(s) against international standards of safety, quality and efficacy. There is a risk that the medicine(s) may; be of poor quality, not conform to label (ingredient and dosage), be contaminated with harmful substances, and/or be counterfeit.**

Guidelines for prescribing medicines ordered on the internet are attached. Additional information on prescribing unapproved medicines can be found at [www.medsafe.govt.nz](http://www.medsafe.govt.nz) under the tab “compliance” and then the tab “unapproved medicines.” The Medical Council guideline “Good Prescribing Practice” may also be of assistance. In order to be fully aware of your rights and obligations we strongly recommend that you read these articles as part of your decision making process.

**Medsafe is not a pharmacy and we do not dispense medicines.** For this reason medicines will not be given pharmacy labels with dosage instructions, so you will need to provide those instructions to your patient in writing.

Yours Sincerely,

Senior Advisor  
Border Control Pharmacist  
Medsafe – Ministry of Health

# PRESCRIPTION

Medsafe Use  
only

Letter to be submitted with consignment

Practice Name, Address  
& Phone Number: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

Doctor's Name & MCNZ#: \_\_\_\_\_

Authorised Prescriber  
Stamp

Patient Name, Date of Birth: \_\_\_\_\_

Patient  
Address & Phone number: \_\_\_\_\_

Brand name	International Nonproprietary Name (INN) – generic name	Dose	Quantity	Frequency of dose (prescriber to complete)	Medsafe Use only

I confirm that:

- The patient named above is under my care
- The medicine, dosage and quantity of medicine listed above is appropriate for the patient
- I have given the patient the dosage instructions in writing
- I have explained to the patient the risks of using medicines acquired from overseas or via the internet
- I accept responsibility for prescribing unapproved medicine to the patient
- The INN is sourced from either Cipla, Hetero, Mylan, Dr Reddy's or Natco for ClinicalTrials.gov Identifier:  
NCT02657694

Tick one of the following<sup>1</sup>

The quantity is three months' supply or less (or six months' supply or less of oral contraceptive pill) and I authorise the medicines to be released to the patient.

The quantity is more than three months' supply (or more than six months' supply of oral contraceptive pill) and I authorise the medicines to be released to my clinic. The medicines will be dispensed to the patient in amounts not exceeding three months' supply or six months' supply for oral contraceptive pill.

Signature \_\_\_\_\_

Date \_\_\_\_\_

<sup>1</sup> More than three months' supply of medicine cannot be released directly to the patient.

**Medsafe contact details. Please include the reference number at top of this letter in all communications.**

Phone: 09 580 9141

Email: medclearance@moh.govt.nz

Fax: 09 580 9198

Postal address: PO Box 7772, Wellesley Street, Auckland

## Prescription medicines obtained over the internet - advice for prescribers

Website: August 2009 Revised 13 June 2013  
Prescriber Update 2009;30(3):17

The internet has now become a significant resource for patients to obtain supplies of prescription medicines from overseas. When these medicines are held at the New Zealand border prescribers are usually asked to provide a prescription to enable their release.

Prescribers are reminded to consider the following prior to providing a prescription for medicines obtained from an overseas source:

- Is this patient under your care?
- Is the medicine, dose and quantity appropriate for the patient?
- Is the patient aware of the risks of using medicines purchased over the internet?
- Are you willing to take on the responsibility for prescribing your patient an unapproved medicine that is likely to be of unknown quality and origin?

Patients who order medicines online commonly believe they are importing genuine branded medicines from countries with highly regulated systems such as Canada or the USA. These websites, which may be linked to spam emails, are sophisticated and misleading as the website may be based in a country different to where it appears to be hosted. A recent study conducted by the FDA of medicines ordered from websites claiming to be Canadian found only 15% of the medicines inspected actually originated in Canada.<sup>1</sup>

Several websites offer medicines for sale without a prescription or in some cases require an online questionnaire to be completed. It is usually not clear whether a healthcare professional is involved in the process.

Medicines coming into New Zealand are intercepted by New Zealand Customs and passed to Medsafe for inspection. Last year approximately 11,000 parcels containing 17,000 medicines were inspected by Medsafe; it is estimated that up to 30% of these medicines may have been ordered over the internet. Medsafe's experience is that many of the prescription medicines crossing the border are of poor quality and may be adulterated or counterfeit. For example, recent testing revealed four undeclared active ingredients in one product ordered over the internet.

The New Zealand medicines legislation requires anyone who imports, distributes, sells or possesses a prescription medicine to have a 'reasonable excuse'. A patient will have a reasonable excuse if a New Zealand registered prescriber has prescribed the medicine. If a prescriber provides a prescription for a medicine that has been intercepted at the border they take on all the responsibilities of prescribing, including responsibility for the quality and appropriateness of the medicine for that patient. Without a prescription a patient is unlikely to have a reasonable excuse and would be in breach of this provision.

In addition to quality concerns, Medsafe is also concerned about the dangers of self-medication. Individuals may not have seen a medical professional, had an adequate diagnosis made, or received information on the risks and benefits of using a particular medicine.

Medsafe advises prescribers to carefully consider these issues before agreeing to authorise supply of a medicine purchased over the internet.

### Reference

<sup>1</sup> FDA (2005). FDA operation reveals many drugs promoted as "Canadian" products really originate from other countries. Accessed 3/7/09 from: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108534.htm>