Key Points

- The quality, safety and effectiveness of generic medicines in New Zealand is evaluated by Medsafe following processes that are at least as stringent as those in Australia, Europe and the USA.
- Medicines that are evaluated as being bioequivalent are very unlikely to have altered clinical effects or adverse effect profiles.
- Generic medicines have been used effectively and safely for many years in many countries, including New Zealand.
- Negative perceptions about generic medicines can influence patient acceptability. Explanation and counseling by prescribers and pharmacists can help to allay concerns.
- Simple strategies such as the doctor prescribing generically and the pharmacist labeling the container with the name of the active ingredient (generic name) can help to avoid patient confusion when brand changes occur.
- Healthcare professionals have an important role in helping patients understand that generic medicines are safe and effective.
- Generic prescribing and dispensing would enable patients to be educated about the names of the active ingredient of their medicine to avoid confusion between different brands of the same medicine.
- Reporting mechanisms are in place (e.g. CARM) to monitor the safety and effectiveness of generic medicines.

Introduction

Generic drugs are reproductions of the original innovator medicine which are made widely available when a drug's patent expires. They have been widely used in many countries for over 40 years, including New Zealand. The use of generic medicines is an important part of health care, providing economical alternatives to more expensive branded products and allowing considerable savings for the overall health care budget. With this potential for savings the use of quality generic medicines is becoming increasingly part of national medicines management strategies. For example, the UK will introduce generic substitution from 2010 and there are similar initiatives in Australia.

We can expect the use of generic medicines to increase in New Zealand. This publication is intended to inform health professionals about the processes by which generic medicines are tested, approved and monitored, to provide reassurance of their quality, safety and effectiveness. As our patients are often misinformed or have concerns about the use of generic medicines we also provide advice on how to increase acceptance of generics amongst patients. Finally, we discuss the monitoring processes in place in New Zealand to ensure that if problems do occur they are identified and resolved in a timely manner.

A few words about the terminology used in this publication. When we mention brand switching it will usually mean a switch from an innovator brand such as the Aropax brand of paroxetine to Loxamine, which is the generic brand. Occasionally, the generic medicine does not have a brand name and may be simply known by the approved chemical name. When bioequivalence studies are described, we refer to the generic compared to the innovator medicine.