

Media Release

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Generic medicines vs branded medicines Bioequivalence explained

The latest issue of ***Australian Prescriber*** addresses the potentially confusing topic of generic medicines and their possible adverse reactions.

The article is written by three distinguished academics – Professor Andrew McLachlan and Professor Iqbal Ramzan from the University of Sydney, and Associate Professor Robert Milne of the University of South Australia.

Generic medicines are usually manufactured after the patent period has expired on branded medicines. “The generic product has to be proven to be bioequivalent to the branded product. This means that they produce such similar plasma concentrations of the active ingredient that their clinical effects can be expected to be the same,” the authors explain. “Generic drugs must also adhere to the strict quality standards set by the Therapeutic Goods Administration (TGA).”

“On scientific grounds there is no reason to be concerned about substituting a generic product for a branded product that is flagged as being bioequivalent,” writes Professor McLachlan.

Switching products that are not bioequivalent may lead to lower or higher blood concentrations of a drug. This may increase the risk of therapeutic failure or drug-related toxicity.

There are some medicines, such as the two brands of warfarin, which should not be substituted as they are not known to be bioequivalent.

“Although generic drugs are bioequivalent, they may have different excipients – such as diluents, binders, fillers, surfactants, lubricants, coatings and dyes,” says Professor McLachlan.

The quality and safety of all excipients are carefully reviewed by the TGA and can only be used if they are safe and non-toxic. There is evidence, though, that excipients may have an impact on patient tolerability. “The main risk is allergy or intolerance to a specific ingredient such as lactose,” he says.

“Before prescribing, it is imperative to consider the patient’s understanding of their medicines and the risk of medication misadventure. Elderly patients, those with cognitive impairment and patients taking multiple medicines for serious chronic illness are at greatest risk,” Professor McLachlan says.

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