

a price difference between generic and branded products.

The pharmacist's profit margin varies from drug to drug and product to product. In the past, cost savings for community pharmacists arose when they purchased bulk orders of generic drugs directly from manufacturers. This issue was not unique to generic products because some manufacturers of branded medicines also sold their products directly to community pharmacies under price-volume agreements. This is one of the many economic issues that community pharmacists have to deal with in the efficient running of their businesses. Recent PBS reforms have created different remuneration schedules for generic and branded medicines resulting in these cost savings now being retained within the PBS.

### Can the bioavailability of bioequivalent products differ by up to 40%?

No, for two drugs to be bioequivalent, the 90% confidence intervals (90% CI) for the ratio of each pharmacokinetic parameter,  $C_{max}$  and AUC, must lie within the range 0.8–1.25 (sometimes also expressed as 80–125%).

The 90% CI of 0.8–1.25 is a numerical index and not a direct measure of the difference in systemic concentrations of the active ingredient resulting from administration of the two products. It does not mean that the  $C_{max}$  and AUC ratios estimated for each formulation can vary by –20 to +25%. In reality, for a product to fit within these relatively tight confidence limits the mean AUC and  $C_{max}$  must be very close, and any difference in bioavailability is certainly less than 10%.<sup>4</sup>

### Conclusion

The bioequivalence criteria used in Australia have been defined and refined over many years and are internationally recognised as the acceptable criteria for assessing bioequivalence.<sup>1</sup> There is persuasive evidence that the current internationally accepted limits and approaches to bioequivalence can accommodate all medicines.<sup>6,7</sup>

Only drugs that are marked as bioequivalent should be substituted for each other. Likewise, drugs that are not bioequivalent should not be exchanged.

To avoid confusion, healthcare professionals should, where possible, reinforce the name of the active ingredient in the medicine, when prescribing, dispensing and administering medicines to patients.

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*Each author has acted as a paid consultant to the pharmaceutical industry (including companies that manufacture innovator branded and generic medicines). Professors Ramzan and McLachlan are also members of the Pharmaceutical Subcommittee, Australian Drug Evaluation Committee.*

## Dental notes

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### Frequently asked questions about generic medicines

Habits formed in the early years after graduation often remain with us during our working life. Despite continuing professional development, when pressed for time or perhaps in a difficult clinical situation, we often revert to practices established early in our professional career. Prescribing drugs by brand name

may be done out of habit, but this may not be in the best financial interest of our patients. We need to continually assess our prescribing habits and consider cost in our choice of drugs. There is usually no reason to be concerned about substituting a bioequivalent generic product for a branded product. To avoid confusion, always tell the patient the active ingredient of the medicine prescribed. When we write a prescription, we are recommending that our patients use a drug, not necessarily a brand.