A drug by any other name... generic and brand-name drugs are clinically equivalent

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The pharmaceutical industry is in the midst of a long, difficult fall from a 'patent cliff'. Over the course of this decade, patents are expiring for numerous 'blockbuster' drugs that once had massive global sales.[1] Because most of the therapeutic and economic return on investment in related drug classes has been extracted, very few new patented drugs are taking the place of these prior blockbusters.[2] This means there are billions—indeed, hundreds of billions—of savings to be had from generic competition in this era.

While increased generic competition is potentially great news for those who pay for medicines, it represents significant losses to the industry and has reawakened a longstanding debate about the equivalence of generic medicines. To this debate, the paper by Lessing et al.[3] published in this issue of the journal adds rather clear evidence on the clinical equivalence of generics. Their study focuses on a class of drugs, antipsychotics, that some might believe are particularly vulnerable to the therapeutic non-equivalents of generics. Their results show that, even for such therapies, there are no statistically significant differences in primary outcomes between generic drugs and their brand-name counterparts.

Given that virtually all generics are bioequivalent to brand-name reference drugs,[4] the results of the study by Lessing and colleagues are not surprising; but they are important. A substantial body of literature, involving many randomised trials and observational studies in real-world contexts, has established that generic drugs are therapeutically equivalent to their brand-name counterparts.[5–7] Yet, despite overwhelming research evidence of interchangeability, many clinicians still doubt such findings.

To be clear, no product, not even an originator brand, will be tolerated by all patients; but differences between generics and brands are not systematic. That is, there is no clinical advantage to one or the other at a population level. There are, however, very significant cost differences at a population level. The advantage goes to generics.

Lessing et al.[3] calculate that switching patients in their study to generic olanzapine saved New Zealand NZ$16 million. That is funding that could be—and likely was—put to productive use by covering other medicines for the population of New Zealand. From an outsider's perspective, this is one thing that New Zealand does better than perhaps any other developed country: it has designed its drug coverage policies with an evidence-based approach and population health perspective, which is to side with the argument that savings generated from policies like generic substitution are essential to an efficient, equitable, and sustainable health care system.

Clinicians and policy makers must, of course, constantly evaluate practices and inform their decisions based on rigorous assessments of bodies of available evidence. As it relates to generic substitutions, even for potentially vulnerable populations, the jury is in: generic and brand-name drugs are clinically equivalent. It is, therefore, prudent to take the savings and invest it in better ways to serve your patients and your population.

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