

Myth

Busters

June 2007

A SERIES OF ESSAYS GIVING THE RESEARCH EVIDENCE BEHIND CANADIAN HEALTHCARE DEBATES

MYTH

Generic drugs are lower-quality and less safe than brand-name drugs

To Shakespeare's Juliet, a rose by any other name would smell as sweet. However, when it comes to prescription drugs and Canadians, there is a lot in a name after all. Although generic drugs are widely used in hospitals, and provincial drug programs try to persuade people to take generic versions of prescription drugs, research evidence suggests some feel uneasy about making the switch.^{i,ii} In addition to concerns generics are less safe and less effective than brand-name drugs,^{i,ii} some patients worry generics cause too many side-effects and are not favoured by their physicians.ⁱ

The problem is worsened by the fact few healthcare professionals initiate conversations with their patients about generic drugs.ⁱ In addition, factors such as patient pressure, a lack of information about generic drugs, and loyalties to drug manufacturers may make physicians more apt to prescribe brand-name drugs,^{iii,iv} which may further instil doubts about generic medicines.

It all can leave Canadians wondering why provincial drug plans have adopted "generics-first" policies, where less-costly but equivalent generic drugs are substituted for brand-name medicines.^v In addition, they may worry that quality and safety are being compromised for the sake of the bottom line.

Different look, same quality

Generic drugs have the same medicinal ingredients as their brand-name counterparts.^{vi} The principal difference between them is that only after the patents on brand-name products have expired may generic companies produce their products.^{vii, viii} Generic drugs are usually less expensive^{ix-xi} – costing on average 45-percent less than the brand-names^{vii} – but may have a different shape or colour than

brand-name counterparts.^{vi} These drugs are often made by large, generic manufacturers. Interestingly, a 2004 estimate finds 27 percent of generic medicines – so called "pseudogenerics" – on the Canadian market are made by brand-name companies.^{xii}

Whoever makes them, all prescription drugs in Canada undergo a review by Health Canada, where drug ingredients are checked and manufacturing processes and facilities are verified against the same federal guidelines.^{v-vii}

Ingredients are the most important element in the review process. Medicinal or active ingredients must meet the same Health Canada standards whether the drug is a generic or brand-name.^{vi, vii} Manufacturers are required to test each drug batch, both during and after production, to demonstrate they are equally safe and effective.^{v-vii} In cases where the generic's non-medicinal ingredients, which give it its colour and shape, are different from the brand-name's, manufacturers must provide research to show the drug meets the standard.^{vi}

Generic drug companies ultimately have two options to prove their products are safe and effective. They may run their own clinical drug trials, repeating most of the testing the brand-name manufacturers have carried out.^{vi} Or they may show how their drug compares with the original brand-name drug in tests of "bioequivalence."^{vi} Most generic drug companies opt for the latter option since the original brand-name drug has already been proven safe and effective.^{vi} If either test proves successful, Health Canada will give its approval, allowing the generic to be substituted for the brand-name.



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Smart substitution

Comparison of prices of four brand-name and generic drugs approved for sale in Canada^{a, b}

Use (form)	Brand-name (strength)	Brand-name price (\$ per single dose ^c	Generic	Generic price (\$) per single dose ^c
Antibiotic (tablet)	Zithromax (250 mg)	4.63	azithromycin	3.11
Cholesterol-lowering (tablet)	Zocor (80 mg)	2.24	simvastatin	1.39
Heartburn (tablet)	Zantac (150 mg)	1.08	ranitidine	0.40
Ulcers (tablet)	Losec (20 mg)	2.20	omeprazole	1.25

^a Each of the drugs in this table has been approved for sale in Canada.^{xii}

^b These drugs were selected from the 200 most frequently prescribed drugs in Canada in 2005 and 2006.^{xiv}

^c Although prices come from the Quebec formulary as of April 18, 2007,^{xv} there is little price variation across provinces. These prices are the wholesale prices and do not include pharmacist mark-ups or dispensing fees. Prices have also been rounded up to the nearest hundredth.

Despite evidence some Canadians may be reluctant to embrace generic drugs, chances are most have taken these medications before. Generic drugs accounted for 43 percent of all prescriptions filled for Canadians in 2005.^{xvi} But generic equivalents are not always available on the market. And some literature indicates there are a minority of cases where changing the drug that is administered may be inappropriate, particularly for drugs that are safe only when a precise dosage is administered.^{xi}

The example commonly cited in the research literature has shown patients with epilepsy may be sensitive to changes in the brand of their anti-seizure medications.^{xi, xvii} However, it also appears there are generics from this class that are safe to substitute.^{xviii} Moreover, there are thousands of generics on the market, all of which appear to be well-tolerated by those who can use them (knowingly or otherwise, as the case may be). While there are always individual differences to how people react to any drug, prescribing generic drugs, where appropriate, can be effective and save money.

Conclusion

Generic drugs must pass the same level of scrutiny from Health Canada as their brand-name counterparts. In the end, consumers and possibly some prescribers may need to rethink some of their assumptions about whether reserving a place for brand-name drugs on their medicine shelf is always best.

Mythbusters are prepared by knowledge transfer and exchange staff at the Canadian Health Services Research Foundation and published only after review by experts on the topic.

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