EDITORIAL

Natural health products should be sold separately from drugs

Matthew Stanbrook MD PhD

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The multibillion-dollar market for "natural" health products has flourished under lax government regulations. These regulations have enabled manufacturers to exploit the public's difficulty in distinguishing nonprescription drugs, with scientifically proven therapeutic benefits, from herbal or homeopathic preparations and supplements that often make similar health claims with little or no evidence and are frequently grounded in unscientific belief systems about health and disease. Health Canada is poised to overhaul its regulatory system for natural health products, which is welcome and long overdue. However, there are troubling signs already that new regulations could be diluted past the point of potency.

In pharmacies, supermarkets and convenience stores, natural health products are displayed side by side with nonprescription drugs. Both tout their approval by Health Canada as an implicit endorsement of efficacy and safety on package labels that make similar health claims. However, although nonprescription drugs and their therapeutic claims require scientific evidence that is carefully scrutinized by Health Canada, natural health products have a separate regulatory system that typically imposes such minimal requirements that it is effectively a rubber stamp. Unlike nonprescription drugs, if a problem arises with a natural health product, Health Canada has little or no authority to compel any changes to its manufacture, labelling or sale.

Under pressure to address these problems, Health Canada has now proposed a new regulatory framework[1] that is intended to hold nonprescription drugs and natural health products to the same standard based on the product's perceived risk profile. Although this represents a laudable step forward, problems remain. Risk is often difficult to perceive accurately without direct evidence. For example, under the proposed framework, Health Canada would continue to classify most homeopathic preparations as low-risk products and, thus, exempt from scientific review. Recently, a homeopathic product sold in the United States that claimed to relieve teething pain in infants and supposedly contained a very dilute extract from the belladonna plant was associated with several deaths of infants who manifested classic signs of anticholinergic poisoning.[2] Like Health Canada, the US Food and Drug Administration has no authority to suspend the sale of this product.

The new framework would also require all health claims on the product to be supported by scientific proof, yet would still permit other "claims" to be made without proof — a loophole ripe for exploitation. Regardless of how product labels are regulated, as long as stores continue to stock natural health products and nonprescription drugs together in aisles labelled according to clinical indications such as "cough and cold remedies," consumers will continue to assume mistakenly that these products all work equally well.

Distinct from the main framework, Health Canada is also "exploring" whether to require a printed disclaimer on all products with claims that are not reviewed by Health Canada, and whether they need additional powers to order the removal of unsafe products from the market, force changes in product labels or levy heavy fines against companies that break the law. Such measures are definitely needed, and Health Canada's perceived hesitancy here is not reassuring, nor is its potential to bow under lobbying pressure. A recent, more limited effort to change labels on natural health products for cough and cold that are targeted at children was watered down after consultations between Health Canada and the homeopathy industry, and remains unenforced.[3]

Health Canada should adopt the proposed changes, but it must go further if it sincerely expects to achieve its stated objective to protect consumers and ensure that they can make informed choices. If consumers are unable to separate products with no scientific proof behind them from products supported by evidence, then we need to separate them in stores. Natural health products should be pulled from the shelves where they are mixed with nonprescription drug products and confined to their own separate section, away from any signage implying a therapeutic use.

The double standard perpetuated by both regulators and retailers that enables the deception of unsuspecting Canadians must end. Alternative medicines with claims based on alternative facts do not deserve an alternative, easy regulatory road to market — at the very least, they need to be moved to an alternative shelf.

References

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Affiliations: Deputy Editor, *CMAJ*

Correspondence to: *CMAJ* editor, pubs@cmaj.ca