

References

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[Dr. Peterson responds:]

Traditionally, physicians and pharmacists have interpreted for patients the technical prescribing information provided by drug manufacturers and approved by Health Canada. More recently, it has become apparent that manufacturers should be providing information more oriented to consumers, to bridge the gap between the technical product monograph and information needed by patients. As a result, a new section of the product monograph, entitled "Information for the Consumer," is required for all new submissions filed with Health Canada as of October 2004.

With regard to the situation raised by Sana Sukkari and Larry Sasich, in 1999 Health Canada notified health care providers, through its *Canadian Adverse Reaction Newsletter*, of 9 cases of hepatic dysfunction in Canada among patients receiving Serzone.¹ In July 2001, Health Canada issued an advisory on the risk of severe hepatic injury with Serzone.²

The product monograph for Serzone was updated in October 2001 to warn of potential hepatotoxicity. This update included a warning to patients that Serzone had been associated with very rare cases of severe liver damage. It advised patients being treated with the drug to seek immediate medical attention if they experienced any of the symptoms on the list provided.

Health Canada reviews and authorizes updates to product monographs and patient information for drugs sold in Canada, and drug manufacturers have a responsibility to ensure that the most recent versions of these documents are released to health care professionals. It appears, for reasons unknown to Health Canada, that the changes made to the 2001 product monograph and information to the consumer were not transmitted for the 2002 and 2003 editions of the *Compendium of Pharmaceuticals and Specialties*. The product was withdrawn from the Canadian market in 2003.

Health Canada continues to pursue initiatives to make product monographs, including information for the consumer, more readily available to the Canadian public. Certainly, the number of notifications to health care professionals about important safety issues — via the Health Canada Web site (www.hc-sc.gc.ca/english/protection/warnings.html) and mailings — reflects the need for physicians and pharmacists to remain current with respect to the drugs they prescribe and dispense.

Robert G. Peterson

Director General
Therapeutic Products Directorate
Health Products and Food Branch
Health Canada
Ottawa, Ont.

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Catering to the customers

It is not surprising that 6 English-language journals published in North America and the United Kingdom would tend to include articles on topics of interest to English-speaking patients, physicians and researchers in those in-

dustrialized, relatively wealthy countries, as reported by Paula Rochon and associates.¹ Grant funding and the subsequent generation of manuscripts, driven by public and political advocacy and commercial interests, probably reinforce this practice.

This is not necessarily good or bad; it is simply a reflection of the professional interests of the readers. One could argue that these journals survive by focusing the bulk of their output on topics that are of interest to the subscribers and advertisers that generate their revenue streams — that's just good business practice.

The conduct and dissemination of a greater number of randomized controlled trials focused on world health priorities may ultimately depend on the development of a comparable research and publishing infrastructure in those less affluent countries, admittedly a daunting task.

Louis B. Jacques

Faculty
Georgetown University
Washington, DC

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[Three of the authors respond:]

Sometimes, it is important to state the obvious, even if it is not surprising. In our study¹ we document that trials published in the leading general medical journals do not reflect the conditions and diseases that are the most important causes of death and disability internationally. Our study points out again the discrepancy between what has priority in North America relative to what is important for most people worldwide.

Even if a problem is obvious, it must sometimes be quantified before the medical community accepts it as a real and pressing issue. Putting numbers to an obvious issue somehow lends it credibility.

We hope our study will have other ef-