Therapeutics Letter

Rofecoxib (Vioxx) withdrawal

Do product monographs adequately inform physicians?

Product monographs are legal documents that in effect transfer responsibility from drug manufacturers to prescribing physicians. At issue is whether the product monographs for rofecoxib and other nonsteroidal anti-inflammatory drugs (NSAIDs) marketed as cyclooxygenase-2 (COX-2) selective NSAIDs adequately inform clinicians about the benefits and drawbacks of these drugs. The Therapeutic Products Directorate at Health Canada has detailed guidelines for preparing product monographs (**www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/product_monograph_e.html**).

Conclusions

Product monographs:

- sometimes provide data about drug harm, including serious adverse events, that is not published elsewhere;
- prove a challenge for finding, extracting, and interpreting the relevant information; and
- inadequately inform clinicians (eg, the rofecoxib monograph gives an incomplete picture of the relative risk of myocardial infarction and total serious adverse events for rofecoxib versus comparable drugs in all trials).

Celecoxib, meloxicam, and valdecoxib 2004 monographs:

- do not claim to improve arthritis symptoms more than non-selective NSAIDs;
- warn against prescribing to patients with a history of peptic ulcer disease;
- do not claim to reduce complicated ulcers as compared with non-selective NSAIDs; and
- provide insufficient information as to whether these drugs increase risk of myocardial infarction or total cardiovascular thrombotic events.

Source: *Therapeutics Letter* 2004;53:1-4. For the complete text of this report, check the Therapeutics Initiative website **http://www.ti.ubc.ca.**

THERAPEUTICS INITIATIVE Evidence Based Drug Therapy

The Therapeutics Letter presents critically appraised summary evidence primarily from controlled drug trials. Such evidence applies to patients similar to those involved in the trials and might not be generalizable to every patient. The Therapeutics Initiative provides evidence-based advice about drug therapy and is not responsible for formulating or adjudicating provincial drug policies.
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