See also page 236

Vioxx°: no surprise...

Just three years ago, in the edition of the French daily newspaper *Le Monde* reporting on the worldwide withdrawal of *cerivastatin*, a cholesterol-lowering drug from Bayer, we predicted that the next "affair" of this type would involve nonsteroidal antiinflammatory drugs, consumption of which was increasing rapidly (1).

We now learn of the worldwide withdrawal of *rofecoxib* (Vioxx°), a nonsteroidal antiinflammatory analgesic belonging to the "coxib" group, leaving millions of perplexed patients (2).

Many commentators may be surprised, seeing this as an isolated case, but prescribers could have predicted the coxib fiasco simply by examining the available data. They could therefore have avoided giving their patients drugs that offer no therapeutic advantages but carry an added risk of adverse effects.

Amid the ostentatious claims of the manufacturers and their supporters, our review articles devoted to these drugs examined the facts, and nothing but the facts. Entitled "*Rofecoxib: a disappointing nonsteroidal antiinflammatory analgesic*" and "*Celecoxib: as disappointing as rofecoxib*", these articles noted that no adequate comparative trials had been conducted during the initial clinical evaluations of these drugs to allow prescribers to judge their beneficial or adverse effects. We concluded that their superiority over conventional NSAIDs had not been demonstrated (3,4).

Following a re-appraisal of the *celecoxib* evaluation data by the US Food and Drug Administration and the real risk-benefit ratio of the coxibs by the European Medicines Evaluation Agency the coxib balloon began to deflate (see pages 226 and 236).

In September, Merck withdrew Vioxx° from the world market after an interim analysis of a placebo-controlled trial of rofecoxib 25 mg in 2600 patients with colonic polyps showed an increased risk of stroke and myocardial infarction (2).

What a shock it must have been for health care professionals who relied on drug companies for their "information"!

And what a shock for university lecturers who based their faith on pharmacological extrapolations and who failed to teach their students to think in terms of patient well-being and risk-benefit ratios rather than effects on organs and cells!

What a shock for those who are supposed to regulate the drugs market and to negotiate prices in keeping with the degree of real therapeutic advance!

What a lashing for hospital and academic professors who assume the role of "opinion leaders" but who in fact act as traders in false ideas and needless risks!

Not to mention the media, who unquestioningly echoed the company's outlandish claims...

For clear-headed health professionals, this episode, just one in a long series, simply serves to reinforce their determination to persuade all those involved in health care to ground their decisions in the evidence and not in commercial fantasy.

Proper patient management requires close scrutiny of all uncertainties and risks, based on reliable and independent information sources.

Lengthy prescriptions listing inadequately evaluated "innovative" drugs are a sign of poor practice, influenced by lobbies and fashions, rather than determined by a strict analysis of benefits and risks.

Hospital professors must stop acting as the mouthpieces for drug companies. General practitioners must stop having their prescriptions dictated by biased professional media and sales reps. Pharmacists must stop passively handing out boxes of drugs. Misinformation to patients and the public must be effectively controlled. And over-confidence in drug company claims cannot be sustained: between the assessment of their own drugs and the search for profitability, companies are subject to unresolvable conflicts of interests.

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1- Bardelay G "Pharmacovigilance: d'une "affaire" à l'autre" *Le Monde* 11 September 2001, page 19.
2- Committee on safety of medicines "Immediate withdrawal of rofecoxib (Vioxx/Vioxxacute)" 30 September 2004. Website http://medicines.mhra.gov.uk accessed on 1st October 2004.
3- Prescrire Editorial Staff "Rofecoxib" *Prescrire Int* 2000; **9** (50): 166-169.
4- Prescrire Editorial Staff "Celecoxib" *Prescrire Int* 2001; **10** (52): 46-49.

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