See also editorial page 202

PRESCRIRE VIEWPOINT

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Coxibs : we want our money back!

The French publicity campaigns for coxib nonsteroidal antiinflammatory drugs (NSAIDs), and especially rofecoxib (Vioxx°, MSD Chibret) and celecoxib (Celebrex°, Pharmacia, then Pfizer), were among the biggest so far this decade. Numerous French opinion leaders had no hesitation whatsoever in declaring that "The coxibs are as effective as conventional antiinflammatory drugs but have far better gastric tolerability" (1).

Our own judgements, reflected in the titles of our articles ("Rofecoxib: a disappointing NSAID analgesic" and "Celecoxib: as disappointing as rofecoxib") stood out in stark contrast to the wildly enthusiastic welcome these coxibs received in the professional and lay media alike (2,3). Yet we were simply pointing out that the clinical evaluation dossiers did not contain adequate comparative data to assess the relative efficacy and safety of the coxibs, and that their claimed superiority over conventional NSAIDs was unfounded.

In France, the companies concerned distributed abundant free samples, or sold their products to hospitals for just one euro cent a dose (4). And they succeeded in obtaining very high prices for their products on the basis of only a modest improvement in "medical benefit" as judged by the French Transparency Commission. For the last three years and until its withdrawal in October 2004, Vioxx° has been sold at 32.70 euros for twenty-eight 12.5-mg tablets and 39.80 euros for twenty-eight 25-mg tablets (5), while Celebrex°, which was marketed later, has been sold at 18.13 euros for thirty 100-mg capsules and 35.20 euros for thirty 200-mg capsules (6).

In 2001 alone, the French national social security refunded prescriptions worth 125 millions euros for Celebrex° (which went in straight at number 3 on the league of drug expenditure) and 29 million euros for Vioxx° (7).

The approval of Vioxx° for symptomatic treatment of rheumatoid arthritis, an indication that already featured on the Celebrex° SPC, was not accompanied by a price cut (8). Worse: the cut that was to have taken place on 3 January 2003 was simply cancelled (9)!

After a reappraisal of the celecoxib dossier by the US Food and Drug Administration, it was revealed that the CLASS study results had been manipulated, raising serious doubts about the claimed advantages of this coxib (10). Methodological flaws were also found in a clinical trial of rofecoxib (11). Meanwhile, negative pharmacovigilance data on the coxibs continued to accumulate (12).

Pressure mounted on the European Medicines Agency (EMEA) to re-evaluate the risk-benefit balance of coxibs. The Agency's conclusions, released in April 2004, were another nail in the coxib coffin. The risk-benefit balance of coxibs was found to be no better than that of other NSAIDs (see page 226 of this issue). On 2 July 2004 the French medicines agency published an update explaining the situation and reminding patients how to use NSAIDs correctly (13).

Following a joint request by French social security and health authorities in 2002, and the EMEA review, the Transparency Commission downgraded Vioxx° and Celebrex°, considering that the "(likely) superiority in terms of gastrointestinal tolerability is minimal" (14,15). Finally the company withdrew Vioxx° in early October due to cardiovascular adverse effects.

In our opinion it is high time the French authorities drew the obvious conclusions: coxibs offer patients no tangible advantage over existing NSAIDs; and the price difference is therefore wholly unjustified. We would also like to know when the companies concerned will be called on to refund the massive over-cost paid by patients and taxpayers, and when the pricing level of remaining coxibs will be brought down to the level of conventional antiinflammatory drugs.

For example, ibuprofen generics now cost about 3.20 euros for thirty 400-mg doses. The Celebrex° price cut on 9 July 2004, provided for in the pricing agreement reached in 2000 (14.87 euros for thirty 100-mg capsules and 29.20 euros for thirty 200-mg capsules) is absolutely ridiculous.

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5- Prescrire Rédaction "Vioxx° remboursable" *Rev Prescrire* 2001; **21** (220): 589-590.
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8- Prescrire Editorial Staff "Rofecoxib in rheumatoid arthritis" *Prescrire Int* 2003; **12** (65): 89-90.
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14- Commission de la transparence "Avis de la Commission - Vioxx°" 16 June 2004: 24 pages.
15- Commission de la transparence "Avis de la Commission - Celebrex°" 16 June 2004: 29 pages.
16- "Avis relatif aux prix des spécialités pharmaceutiques" *Journal Officiel* 9 November 2000: 17791.

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