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Shocking market approval

Paliperidone, the main active metabolite of risperidone, one of many available neuroleptics, is now approved for sale in Europe for patients with schizophrenia (see page 236 of this issue). The sole reason for the incarnation of this metabolite as a 'new' treatment is commercial. Shockingly, this decision was based solely on placebo-controlled trials: there were no trials comparing paliperidone to standard treatments - including risperidone, although for over 50 years neuroleptics have been shown to relieve these patients' symptoms. The governments and drug regulatory agencies bear a large share of the responsibility for this situation, as they unquestioningly follow regulations that fail to consider the importance of therapeutic advantage. Similarly, drug companies only conduct the minimum of studies required to ensure their products get to market as quickly as possible, without any unwelcome surprises.

What is most shocking is that doctors agreed to enrol acutely ill patients in placebo-controlled trials, fully aware that some of them would be deprived of an active treatment. And they could not even pretend to themselves that these trials might somehow improve the management of schizophrenia.

The same situation occurred with etoricoxib (see page 223). Patients were again deprived of the best available treatment, only in order to fill the ranks of clinical trials that had no serious chance of improving patient management.

Mercenary? Perhaps. Shocking? Absolutely! If healthcare professionals are prepared to withhold effective treatment from patients with a disease as serious as schizophrenia, simply in the name of commercially driven clinical trials, something is seriously wrong and changes are urgently needed.

There is an urgent need to remind drug regulatory agencies that their public health responsibilities mean more than minimal compliance with regulations. Healthcare professionals must also be reminded of their professional responsibility to help patients. They must refuse to prescribe a placebo when an effective drug is available. And they must refuse to participate in corporate-sponsored "research" that leads to over-medication of the ups and downs of life, and puts profits before patient health.

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