Translated from *Rev Prescrire* July 2008; 28 (297): 535

Premature marketing authorisation: danger

In recent years the approval process for new drugs has accelerated. This is a result of both strong pressure exerted by drug companies, and attempts by weak-kneed authorities to pander to the pharmaceutical industry and some members of the public seeking ever-earlier access to "innovation".

In the United States, legislation passed in 1992 linked an increase in private sector funding of the Food and Drug Administration to more rapid processing of marketing applications. The FDA is now required to examine 90% of applications within 10 months, and applications for "priority" drugs within 6 months (1).

A revealing study. A university research team investigated a possible link between the legally required time for approving a new drug and post-marketing safety issues (1). The study focused on 313 drug licences granted between 1992 and 2005. The results speak for themselves.

Compared to drugs that were granted marketing authorisation after the legal deadline, drugs authorised within the 2 months before the legal deadline were 6 times more likely to be withdrawn from the market because of safety issues, and 4 times more likely to trigger major safety alerts once on the market (a black box warning added to the packaging, signifying a special need to report adverse effects). There were also 3 times more market withdrawals of one or more dose strengths for safety reasons (1).

Public responsibility, public funding. These results confirm that marketing applications for drugs must be meticulously examined, and that granting premature marketing approval places patients at an increased risk of adverse effects.

The results of this study are contributing to the sharp criticism of the FDA and its lack of public funding (2). More and more US commentators and decision-makers are starting to realise the damage caused by drug company influence on drug policy. The Vioxx° affair and other scandals are fuelling a heated debate. The authorities are coming under fire for failing to protect the public.

After its political failure in 2001, and despite a plethora of health scandals, the European Commission is still seeking to relax and accelerate the drug approval process (3,4). It even wants drug companies to have more control over pharmacovigilance.

If the authorities are incapable of protecting the public from the dangers of premature marketing authorisation, civil society and ordinary citizens must remind them of their responsibilities.

Prescrire

Selected references from Prescrire's literature search.
1- Carpenter D et al. "Drug-review deadlines and safety problems" *N Engl J Med* 2008; **358**: 1354-1361.
2- "The FDA in crisis : it needs more money and talent" *New York Times* 3 February 2008. www.strengthenfda.org accessed 2 April 2008: 2 pages.
3- Editorial Staff "Medicines in Europe: the most important changes in the new legislation". www.prescrire.org/aLaUne/dossierEuropeSynthese2En.php
4- Press release "Pharmacovigilance in Europe: overwhelming opposition to the EU Commission's proposal" www.isdbweb.org