Prescrire International Editorial

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Malfeasance on an industrial scale

"*For a long time, our health care system had been a target for cheaters who thought they could make an easy profit at the expense of public safety"* (1). These were the words of the US Deputy Secretary of the Department of Health and Human Services in July 2012; and they were aimed at pharmaceutical company GlaxoSmithKline (GSK).

A record fine for GSK, notably for failure to report information. In mid-2012, GSK agreed to pay 3 billion US dollars to put an end to several lawsuits brought by the US authorities (1). The grounds included failure to report to the US Food and Drug Administration (FDA) the adverse cardiovascular effects of *rosiglitazone*, misleading and off-label promotion of the antidepressant *paroxetine* for children under the age of 18, promotion of *bupropion* (Wellbutrin°, authorised in the USA for depression and Zyban°, approved in France for smoking cessation) outside the approved indications, for weight loss and to enhance sexual performance (1,2).

The US consumer advocacy group Public Citizen says that the criminal fines are not sufficiently dissuasive, in comparison to the profits generated. The group is calling for prison terms to punish actions that are hazardous to patients' health (3).

Roche: adverse effects not studied and not reported. A routine inspection carried out in 2012 for the European Medicines Agency (EMA) revealed that the pharmaceutical company Roche neither analysed nor reported to drugs authorities more than 80 000 suspected cases of adverse drug effects, including more than 15 000 in patients who had died (4).

Pharmacovigilance is mission impossible for pharmaceutical companies. Both of these examples demonstrate yet again just how far removed pharmaceutical companies' rhetoric about their role as "health partners" is from their actions.

Companies have a clear interest in minimising or even concealing the adverse effects of their drugs. Healthcare professionals, governmental institutions, those who finance the cost of healthcare systems and who, for a variety of reasons, wish to see companies involved in providing information to patients and to the general public, or who feel that pharmaceutical companies have a central role to play in the pharmacovigilance system, are exposing patients to unacceptable risks.

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Selected references from Prescrire's literature search.
1- "GSK plaide coupable et paie une amende record" 3 July 2012. AFP report 3 July 2012: 1 page.
2- "GlaxoSmithKline to plead guilty and pay $3 billion to resolve fraud allegations and failure to report safety data". www.justice.gov accessed 30 July 2012: 3 pages.
3- Wolfe S "GlaxoSmithKline settlement still not enough to deter illegal behavior by pharmaceutical industry". www.citizen.org accessed 26 July 2012 : 1 page.
4- "European Medicines Agency acts on deficiencies in Roche medicine-safety reporting". www.ema.europa.eu accessed 26 July 2012: 2 pages.

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