Prescrire International Editorial

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Adverse effect reporting: pharmaceutical companies can't be trusted

In the United States, Europe and elsewhere, public authorities have a tendency to rely on pharmaceutical companies for the collection and analysis of the adverse effects of drugs (1). Yet a number of scandals have shown that companies sometimes engage in massive cover-ups of adverse effects (2). Are these scandals exceptions to an otherwise acceptable state of affairs?

Incomplete reports. The US Institute for Safe Medication Practices (ISMP) analysed the data collected between 2013 and 2014 by the US Food and Drug Administration's pharmacovigilance system (3). About 29 000 of the 847 000 reported adverse effects had been submitted directly by patients and healthcare professionals, while the vast majority (96.5%) came from drug companies (3).

The reports submitted by patients and healthcare professionals were more complete than those submitted by drug companies: for example, 81% of reports included the age and sex of the patient affected and the date of the report, versus only 46% of reports that emanated from pharmaceutical companies (3).

Surprising laxity. In the case of the most serious adverse effects, requiring expedited reporting, the situation was hardly better: 85% of reports from patients and healthcare professionals were reasonably complete, versus 49% of reports submitted by drug companies (3).

In addition, drug companies frequently reported information of little relevance, such as *"injection site pain"*, an unspecified *"adverse event"*, *"nasopharyngitis"* or even *"no adverse event"* (3).

Drug companies did not provide sufficient information in patient death reports. In 28% of cases, it was impossible to determine whether the drug had played a role, and 67% were of only *"limited value"* for analysis of a possible drug role (3). Only 25% of reports of birth defects were sufficiently complete for analysis (3).

Do not expect drug companies to provide high quality data. In summary, this new study and many years of experience show that drug companies cannot be relied upon to provide high quality data on the problems caused by their drugs. And it is unacceptable that public authorities still count on drug companies to develop pharmacovigilance, and sometimes even consider relaxing the requirements for pre-marketing clinical trials of drugs. Pharmaceutical companies should not be responsible for determining the safety of their own products, given the inherent conflict of interest.

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Selected references from Prescrire's literature search.
1- Prescrire Editorial Staff "European pharmacovigilance: increasingly outsourced to drug companies" *Prescrire Int* 2014; **23** (155): 302-307.
2- Prescrire Rédaction "Malfaisance à l'échelle industrielle" *Rev Prescrire* 2012; **32** (349): 853.
3- ISMP "A critique of a key drug safety reporting system" *QuarterWatch* 2015: 22 pages.

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