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Bias in company-sponsored epidemiological studies

● Evidence from oil and chemical industry.

Epidemiological studies funded directly or indirectly by drug companies or the organisations lobbying on their behalf often provide "convenient" results.

One review of studies of exposure to certain chemicals (alachlor, atrazine, formaldehyde and perchlorethylene) showed that 60% of studies conducted by researchers independent of industry found these chemicals hazardous to health, compared to only 14% of industry-sponsored studies (1).

Other investigators examined epidemiological studies funded by the oil industry and found a number of biases that tended to make the results more favourable to industry (**a**)(1).

Dilution. One source of bias consists of studying all workers in a given company instead of only those exposed to the product in question. This has a diluting effect that seriously underestimates the risk (1).

Misclassification bias. A second potential bias can arise when exposed and unexposed workers are misclassified, with some exposed workers included in the control group. This practice has been known to lead to the somewhat surprising conclusion that exposed workers are healthier than their unexposed colleagues (1).

Inappropriate choice of controls. A third source of bias occurs when the "healthy-worker" effect is not taken into account.

This can happen when the frequency of a health disorder in exposed workers is compared with that in the general population rather than in a group of unexposed workers. In fact, workers on average tend to have better health than the general population, as health is a prerequisite and a selection criterion for work (1).

Many other biases. Other tricks consist of selecting exposure to one substance rather than to other substances that can interact with it; to interpret lack of monitoring as a lack of exposure; and choosing an observation period that is too short for long-term risks such as cancer to develop (1).

Who pays the piper… The authors of this study conclude by calling for truly independent research, without industry funding. This is the only condition under which health risks can be properly assessed and prevented (1,2).

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a- One author of this study, Lorenzo Tomatis, was among the first scientists to be employed by the International Agency for Research on Cancer (IARC), and subsequently served as its director from 1982 to 1993 (ref 2).

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The EMEA should stop promoting brand names

● Use the INN system!

A drug's International Nonproprietary Name (INN) is its real name. The brand name simply refers to a particular commercial product.

Drug companies naturally promote the use of their brand names, but what is surprising, and unacceptable, is that certain public assessment reports issued by the European Medicines Agency (EMEA) also make frequent use of the brand name. Thus, in the assessment report on *lacosamide* dated 29 August 2008, *lacosamide* is designated 263 times by its INN but also 141 times by the brand name Vimpat°, i.e. 35% of the time (count based on the "advanced search" option of the Acrobat Reader° 9 program; see this issue page 196).

When we questioned EMEA, we were simply informed that "*as the assessment does not only refer to the active substance, but to the whole product as it is manufactured and tested, it is important to reflect the invented name on the European Public Assessment Report (EPAR)*"; the case of *lacosamide* was not specifically mentioned (1). One wonders who actually wrote this assessment report.

In the report on *rivaroxaban*, the INN is used 433 times and the brand name Xarelto° 16 times (less than 4%) (see *Prescrire International* issue 102, page 151).

Similarly, in the report on *tocilizumab*, the INN appears 204 times and RoActemra° 14 times (6%; see this issue page 198).

The European Medicines Agency must stop promoting the brand name Vimpat° in their assessment report on *lacosamide*. The Agency's mission is to promote and protect public health, not the economic interests of drug companies.

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1- European Medicines Agency "Request on Vimpat" E-mail to *Prescrire* 19 January 2005; 1 page.

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