Translated from *Rev Prescrire* September 2009; 29 (311): 641

Putting temptation in their path

The adverse effects of drugs are obviously a problem for patients, who expect reasonably effective treatments without exposure to disproportionate risks. Instead, patients are often the victims of adverse effects, sometimes without having obtained any benefit at all from treatment.

Adverse effects are a problem for health professionals, who often rely on drugs to provide effective treatment for their patients. Instead, they are sometimes faced with damage that they may have failed to prevent, or that they may even have caused.

Adverse effects are a problem for the pharmaceutical companies, as a slump in drug sales threatens profitability.

Adverse effects are a problem for health insurance organisations, which have to pay health costs they were not able to anticipate.

And they are a problem for governments, which have a duty to ensure the health and safety of the public.

Adverse effects are rarely discussed. Medical students receive little professional training on the subject of adverse effects, either as part of their initial or continuing education. They receive very little training on pharmacovigilance, either at university or when in clinical rotations in hospital. Neither the basic concepts underlying drug safety surveillance nor measurement techniques are well known. Reporting of adverse events is not really encouraged.

Faced with this problem, the European Commission is proposing a new directive and regulation.

But with the aim of causing as little disruption as possible. While spending as little public money as possible. And ignoring the causes of the problem. Even if this means aggravating the situation and disregarding the long-term implications for public health and safety. The Commission nonchalantly proposes to hand over the problem to those who have the most to gain by hushing it up: pharmaceutical companies.

Drug companies are already responsible for evaluating their drugs before they are marketed (drugs on which the companies' profits depend), with the risk they may withhold crucial information. Instead of acting to reduce this conflict of interest, the Commission proposes to give pharmaceutical companies the additional responsibility of evaluating drugs after they are on the market.

Instead of strengthening the existing network of independent pharmacovigilance centres, the Commission proposes to bypass it.

Instead of improving the information provided to patients and health professionals, the Commission proposes to give drug companies a totally unwarranted stranglehold on sensitive data.

By outsourcing pharmacovigilance to the pharmaceutical companies, the European Commission, and those who allow it to do so, are putting temptation directly in their path.