Prescrire International Editorial

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Reporting adverse effects is essential

In order to prevent avoidable drug-induced harms, drugs must be thoroughly evaluated before their market introduction and then subjected to robust post-marketing pharmacovigilance that is independent of the pharmaceutical industry.

Yet new European regulations have heavily outsourced the surveillance of the adverse effects of drugs to the very companies that sell them. Pharmaceutical companies now collect reports of adverse effects, enter them in a centralised database, and interpret them, providing drug regulatory agencies with a "*benefit-risk evaluation*" of their own products. Drug companies therefore have control over pharmacovigilance data at each of these stages (see in a coming issue). They also finance the pharmacovigilance activities of the European Medicines Agency through the fees they pay (see p. 302).

Faced with a situation in which pharmaceutical companies assess the very drugs they sell, and in which drug regulatory agencies' responsibility for drug safety is being eroded, healthcare professionals and patients can only rely on themselves. When certain symptoms occur, they need to ask themselves whether a drug could have been responsible, and then routinely report suspected adverse effects to pharmacovigilance centres. Spontaneous reporting remains the cornerstone of pharmacovigilance.

A small series of properly documented cases is often sufficient for detecting a new adverse effect. And in this era of electronic mailing lists, by sharing observations with other patients, other healthcare professionals, or one's network of contacts, it is sometimes possible to gather and submit additional data to the authorities in order to encourage them to take action.

It is crucial that information collected at the local level is sent to regional pharmacovigilance centres, and then on to national drug regulatory agencies and the European Medicines Agency. Healthcare professionals and patients must also demand that health authorities provide them with feedback and access to the data in pharmacovigilance databases that they have helped compile.

Through reporting adverse effects, sharing our experiences, looking for specific adverse effects associated with a given drug, including retrospective reviews of patients' records, and publishing these findings, we can all participate in improving collective knowledge about drugs and how to use them better. If we are to get the most out of drugs, it is up to each of us to play an active role in independent pharmacovigilance, in the interests of patients.

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