Prescrire International Editorial

Translated from ***Rev Prescrire*** **November 2011; 31 (337): 801**

Daring to take action, daring to be unpopular

French regional pharmacovigilance centres have plenty going for them. They possess real expertise in assessing reports of adverse drug reactions. They are close to the healthcare professionals who care for the patients hospitalised for adverse drug reactions. This proximity puts them in a good position to encourage reporting and to collect the data from patient records that allow for precise descriptions of adverse drug reactions.

Pharmacovigilance teams bring together physicians and pharmacists who are involved in teaching pharmacology. This allows them to put clinical and pharmacological data into perspective. So, for example, if reports of heart valve damage attributed to benfluorex are to be of value, they must be gathered and interpreted with respect to the known pharmacodynamics of this drug. Regional pharmacovigilance centres are ideally placed to fulfil this role.

However, multidisciplinarity, proximity and technical expertise alone are not sufficient to carry out pharmacovigilance centres' most basic role: to help protect patients from unwarranted adverse drug effects.

This requires that each individual make the best use of his or her skills, while keeping priorities focused on patients' interests. Which includes daring to be unpopular. Without hiding behind regulations, behind the authority of the agencies that grant marketing authorisations, or behind European authorities. By speaking out against unfounded or biased decisions made under the influence of drug companies, or under other influences that are contrary to the public interest.

Over and above structural changes, what is most needed is a marked change of mentality. Everyone must insist upon, and practice, transparency and full access to all data that is useful in evaluating adverse effects.

When a drug's harm-benefit balance is unfavourable, or unclear in comparison to another available drug, it is unwise to postpone a decision by requesting a new study or a new expert report. This is falsely reassuring, while leaving patients exposed. It is disturbing indeed to set aside reports and epidemiological studies because of their limitations, and on the basis of uncertain causality: when there is doubt, the scales should tip in favour of patients' welfare.

The regional pharmacovigilance centres that truly carry out their intended mission act as a vital shield protecting the health of patients.

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