Are suspected adverse drug effects described in the same way by patients and health professionals? Is the description modified by coding for inclusion in a pharmacovigilance database? And does patient reporting add anything useful to reports by health professionals?

British authors compared two sets of reports of adverse effects associated with paroxetine, a selective serotonin reuptake inhibitor antidepressant (SSRI) (1,2).

The first set comprised 1374 e-mails that were sent spontaneously by patients or their relatives to BBC-TV in response to a documentary on the adverse effects of paroxetine (3), and 862 e-mails sent to an interactive discussion board (Adweb) for people taking SSRIs, placed online before the BBC programme was aired (3).

The second set was made up of 1555 case reports (Anonymised Single Patient Printouts or ASPPs) describing suspected adverse effects of paroxetine that had been transcribed from reports (Yellow Cards) by British health professionals to the Drugs and Healthcare Products Regulatory Agency (MHRA) (4). It was the first time the Agency had communicated to a third party data contained in the British pharmacovigilance database ADROIT (Adverse Drug Reaction Online Information Tracking database) (4).

Patients’ reports drew attention to previously overlooked events. In particular, there were 13 deaths by suicide considered surprising by the relatives, 47 suicide attempts, and 92 cases of self-harm or violent acts. This violent behaviour seemed to occur mainly at the beginning of treatment, after a change in the dose, or during weaning.

As this link had not initially been spotted by the British agency, the authors analyzed 91 cases reported by health professionals describing suicides or suicidal behaviour by patients taking paroxetine. The authors found evidence to support the link in more than half the cases.

An “electric head” sensation during treatment withdrawal. There were many reports of withdrawal symptoms after paroxetine treatment was stopped, both in the e-mails received by the BBC and Adweb. Even e-mails to the BBC from people with a positive opinion of paroxetine described problems on treatment withdrawal in 40% of cases. The authors discovered that the most common withdrawal symptoms included an electric head sensation, associated with sensations of whistling and dizziness. Patients reported that these symptoms were alarming and incapacitating.

An inadequate coding system. The authors looked for similar descriptions of “electric head” in the British agency’s case reports (ASPPs). They found 52 such cases reported by health professionals, but these had been coded as “paresthesia”. In the light of the e-mails sent to the BBC, the authors considered that this serious symptom, which many patients said made it difficult or impossible to stop taking paroxetine, should be given a more explicit code than “paresthesia”.

Numerous consistent patient reports must be taken seriously. Independent patient reports, especially when numerous and consistent, must be taken seriously by health authorities.

The British patients in this study described their behaviour and sensations more precisely than the health professionals. And an analysis of the reports received by the BBC-TV threw new light on information that was contained in reports by health professionals but that had been overlooked.

Patients reporting must be organised. While the principle of patient reporting of adverse effects has been accepted by 23 countries (2), it is not covered by the new European legislative framework (4).

An official British report published in May 2004 on providing access to pharmacovigilance (Yellow Card) data for researchers and public health bodies recommended creating a national system for collecting patient reports, within the British agency (5).
The agency agreed, announcing that it would launch pilot studies (6,7).

With some exceptions, such as collation of adverse events related to antiretroviral drugs and reported by HIV-infected patients to the French medicines agency (8), a few pilot trials (7), and the promising example of the British Drugs and Health Care Products Regulatory Agency, national health authorities in general appear to treat individual patient reports as barely credible and anecdotal (e)(2).

The British study of paroxetine reports shows that spontaneous reports from health professionals and patients are complementary. It should encourage all national health authorities to set up practical means (specific forms for consumers, pharmacovigilance consultations) by which patients can directly report suspected adverse effects. These reports should be treated transparently and rigorously, in the same way as all other pharmacovigilance data.

Selected references from Prescrire’s document watch.
4- Prescrire Rédaction “Europe et médicament: les succès obtenus par les citoyens” Rev Prescrire 2004; 24 (252): 542-548. [see printout of August 2004 issue “Medicines in Europe: the most important changes in the new legislation”, and www.prescrire.org]
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7- Williams K “Patients will be able to report drugs’ side effects” BMJ 2004; 328 (7448): 1095.
8- Prescrire Rédaction “Notifications directes par les patients” Rev Prescrire 2002; 22 (234): 827.

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