Des: an ongoing disaster

Diethylstilbestrol (DES) was used from the 1950s to the late 1970s, “to prevent miscarriage”. Yet it was shown to be ineffective in this indication as early as 1953. In 1971, an increased risk of vaginal cancer was reported among women whose mothers had taken DES during pregnancy. DES continued to be prescribed to pregnant women until 1981 in France, where an estimated 160,000 people were exposed to the drug in utero (see page 264 of this issue).

The list of adverse effects attributed to prenatal DES exposure continues to grow. In addition to its adverse effects on the genitalia of “DES sons” and especially “DES daughters”, both men and women exposed to DES in utero now appear to be at an increased risk of psychological disorders.

DES is therefore a drug that continued to be used long after it had been shown to be ineffective, and even after it had been shown to have severe adverse effects. Thirty years after DES was withdrawn from the market, it is still provoking serious adverse effects.

The DES disaster occurred because drug companies, regulatory agencies and healthcare professionals failed to assume their responsibilities. And the more recent Mediator° (benfluorex) and Vioxx° (rofecoxib) scandals show that important lessons have still not been learnt.

All healthcare professionals need to reflect on their individual responsibilities, including long-term consequences, when they prescribe or recommend a drug. It is crucial to base treatment decisions on the evidence, and not just on “official” or regulatory information: the Mediator° scandal illustrates just how misleading official recommendations can be.

Healthcare professionals and regulatory agencies need to reconsider the concept of “risk”. The greatest risk for a patient is to be needlessly exposed to the adverse effects of a treatment which has no proven efficacy, as was the case with DES and Mediator°. This is an argument for requiring thorough evaluation of all new drugs before they are granted marketing approval.

When several therapeutic options are available, healthcare professionals must base their choice on a number of principles, the first of which is “to do no harm”. They must systematically question official decisions, “expert” opinions and marketing materials with a critical mind. They must inform patients of the expected benefits and potential harms of their treatments and listen to their feedback.

These are some of the principles that Prescrire has upheld over the years, principles that should be stressed in medical and pharmacy schools.