# Safety signals: why bother?

A drug is a serious affair. With serious medical and ethical aspects, as well as economic and financial implications, to consider. It is the culmination of lengthy research in the laboratory, then in volunteers, then in a limited number of patients, and then in hundreds, if not thousands, of patients who agreed to take part in comparative clinical trials and, in so doing, helped build the evidence base. And then there are risk management plans, meta-analyses, pharmaco-epidemiology, specialty society guidelines, and so on.

When the first safety signal appears, it would be unreasonable to tear down all that has been accomplished and waste all of the economic benefits at the drop of a hat. By hastily and lazily applying the precautionary principle, in the heat of the moment, without a systematic analysis or longer-term data (see "When to take a safety signal into account: Prescrire's experience" p. 21 of this issue).

On the face of it, the easier choice is to ignore or be unaware of safety signals. For patients, who leave it to health professionals to provide high-quality care (it's their job). And for healthcare professionals, who entrust the issue of safety signals to drug regulatory agencies (it's their job, as the "drug police"), pharmaceutical companies (it's their drug, so it's their job) and guidelines (which are based on all of the above).

The trouble is that pharmaceutical companies are well aware that simply mentioning an adverse effect in the drug's summary of product characteristics (SmPC) and patient information leaflet affords ample protection against legal action in Europe. Even the most concise of statements, buried in a mass of other information, is sufficient to refute the argument "*nobody told us*".

Another problem is that, with so many drugs to manage and limited resources, regulators struggle to put pressure on companies to be loud and clear about the dangers of their drugs, or to deal with the fallout when a public health crisis suddenly brings these dangers into the spotlight. And reconsidering one's position can be uncomfortable.

Then what can be done? Simply make decisions through force of habit? Let the authorities decide? Or adapt our decisions to put the individual patient's interests first?

In other words, choose to be a prudent healthcare professional who knows that too many pharmacovigilance disasters were foreseeable well in advance if safety signals had been heeded, who knows that bad things do not just happen to other people, and who stops to think "*I wonder if Mr So-and-so's lung problems, which show no sign of letting up, could be due to his anticoagulant, like those cases observed in Taiwan?*" (See "Xabans: interstitial lung disease" p. 19 of this issue).

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