Balancing safety against need

Kathy Redmond ■ EDITOR

When Pfizer followed Merck & co in withdrawing one of their COX-2 inhibitors from the market owing to increased risks of cardiovascular complications, it provided a timely reminder that medicines are not without their risks. We have known about the potential harm associated with medicines for centuries. Almost 500 years ago Paracelsus wrote: *Dosis facit venenum* (the dose makes the poison) – in other words, the higher the dose of any particular chemical, the greater its toxic effect on living organisms. Beneficial medicines can turn poisonous if you take too much – low-dose aspirin can reduce heart disease but higher doses can kill.

Ideally, we should protect patients from harm, but in reality, when most novel medicines are approved it is impossible to know enough about their long-term effects to enable us to do so. Gathering sufficient information prior to approval could delay access to potentially useful therapies for patients with no other options – a delay some cancer patients cannot afford. The introduction of innovative medicines requires that regulators strike the right balance between risk and benefit. With life-threatening diseases it is more acceptable to take risks with safety because so much more is at stake. Communication between pharmaceutical companies, regulators, patients and other stakeholders is essential in order to get the balance right. This is because risks are experienced and interpreted very differently depending on the perspective of the observer, and the way risks are perceived can also vary significantly depending on the situation. Once a medicine reaches the market its safety should be continuously monitored and efforts made to ensure that it is used appropriately in clinical practice. Additional clinical trials need to be carried out to clarify the effect of exposure to the medicine in 'real life' situations and to define new indications. Better mechanisms are needed for reporting adverse drug reactions and we need to raise professional and public awareness about potential safety concerns. In its recent 'Road Map to 2010' the European Medicines Agency has made a commitment to ensure that patients suffering from life-threatening conditions will gain timely access to safe and effective medicines. The Agency also aims to introduce more proactive approaches to pharmacovigilance across the EU. These developments are welcome, for it would be a tragedy if ill-informed risk-benefit analyses hindered the approval of innovative cancer drugs that could benefit thousands of European patients, or if effective medicines have to be withdrawn because we did not get the monitoring right.

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