

Is it safe?

Priority Medicines for the citizens of Europe and the World asserts that current regulatory practices are a barrier to innovation. The complaint is that »regulatory authorities are becoming more risk-averse« [p111] and adopt measures beyond those strictly necessary to protect safety. Regulatory practices can be slimmed down to stimulate innovation and get products on to the market more quickly, without compromising safety. But this amounts to a shift from authorising new medicines only when they have proven to be safe, to authorising them until they can be proven to be unsafe. HAI Europe contends that new medicines should only be authorised and prescribed on the basis of the fullest possible analysis of benefit and risk.

The blame for a lack of innovation in the pharmaceutical industry is laid squarely at the door of drug regulatory authorities. Particular attention is given to blockages due to »preclinical regulatory »rituals« [p110], dated methodologies which often fail to predict safety problems that later lead to a drug's development being stopped or its authorisation withdrawn. Positive examples are cited of the fast-track approval of drugs for AIDS and some orphan diseases, where use with patients with no other treatment options is granted prior to full market authorisation.

Priority Medicines proposes to build on this example and test each element of the regulatory system for relevance, cost and necessity. Cuts identified in time taken to get new medicines onto the market are not felt to equate to cuts in the rigour of safety assessments. Running post-marketing comparative trials to ascertain whether a new medicine is better than an existing medicine – and better enough to justify any extra cost – is meant to serve as an alternative safety net. Reference is made to the need to build up and integrate databases of adverse reactions [pp111,127], but the focus is very much on comparisons of cost and efficacy, »to reduce pre-marketing regulatory requirements and speed up the market entry of new medicines« [p127].

What Health Action International Europe says:

HAI Europe fears that a model of medicines research geared towards scaling down safety checks and which does not adequately address the problem of how to receive and respond to reports of adverse reactions can expect to generate more cases of drugs demonstrably doing more harm than good.

HAI Europe:

- agrees that there is a need to continually develop and refine tools for assessing safety and efficacy of medicines. But the precautionary principle, that drugs should only be authorised for use once demonstrated to be safe, must be upheld.
- stresses the reality that »selective reporting of trials does occur and it distorts the body of evidence available for clinical decision-making«¹. These distortions run deep – the pharmaceutical industry often funds researchers or establishes research institutions and keeps secret new information discovered by its »own« scientists. Skewing basic research towards market priorities affects the quality of data then used in translational research and critical path development.

To reassert the primacy of safety in decisions about whether medicines are approved, Dutch and subsequent European Union presidencies should:

- ensure that regulators and doctors are kept free of the influence of medicines producers to allow judgements of suitability and safety of medicines to remain free of prejudice;
- advise regulators to err on the side of protecting patients rather than seeming to hope that a problem will turn out not to be serious;
- insist that pharmaceutical companies publish all clinical trial data;
- invest in pharmacovigilance and actively encourage patients to report the adverse effects of medicines and
- establish suitable mechanisms to ensure their reports are not ignored or distorted by doctors, regulators or the producers of medicines.

¹ Editorial signed by 11 leading medical journals, 9 September 2004