

## Can I trust you?

*Priority Medicines for the citizens of Europe and the World* offers a model of getting medicines to market faster by speeding up regulatory processes and extending post-marketing surveillance as a safety net to protect patients. This model is predicated on assumptions about the value of medicines; these assumptions are promoted to patients and doctors in ways which are often unhelpful and at times manipulative. That the model aims at increasing patient choice and involvement in all stages of medical research and production disguises its driving rationale of private sector profit, not public health benefit.

## What Health Action International Europe says:

HAI Europe agrees that greater patient involvement in medicines' production could improve regulatory processes, and could improve the ways patients use medicines. However, it is not necessarily the case that new medicines provide increased therapeutic value for patients. Nor is it the case that medicines are the best intervention for many health conditions. Furthermore, patients are (as a matter of course) vulnerable to suggestion. So it is important to ensure that patients get complete and honest information about the medicines they use.

HAI Europe recommends that in terms of public involvement in clinical trials and medicines regulation:

- The advancement of science depends on the willingness of the public (both healthy and sick) to donate their bodies to science.
- The value of public involvement in science depends greatly on the quality of information available about the risks and benefits of their involvement in clinical trials and on the appropriate establishment of regulatory standards. Good information depends in turn on the independence of regulatory bodies from the producers of medicines.
- The information generated from public involvement in trials – both positive and negative – must remain available to the public, and must be subject to review from independent authorities.

In terms of patient involvement in post-marketing surveillance of medicines:

- If patients are to be encouraged to report the adverse effects of medicines they use, then suitable mechanisms must be established to ensure their reports are not ignored or distorted by doctors, regulators or the producers of medicines.
- Equally, regulators and doctors must be kept free of the influence of medicines' producers, to allow judgements of suitability and safety of medicines to remain free of prejudice.
- The recent examples of anti-depressants and Vioxx, demonstrate the regulators' slowness to respond, and lack of vigilance.
- Databases that record patient experiences of the use of medicines must be maintained by independent bodies, taking into account the ethical implications of the availability of such information to third parties (in particular the industry and insurers).

In terms of information to patients through the media:

- The vulnerability of the public and patients means that great care must be taken that the information they receive is not misleading or distorted.
- Where other interventions than medicines are available for particular health problems (such as prevention or alternative therapies), patients and the public must be able to compare their relative value, benefit and risk.
- As such, HAI Europe calls for the provision of independent comparative information about interventions for disease, including comparative information of medicines to treat the same condition, that includes the fullest analysis of benefit and risk.
- Stringent guidelines must be established to regulate information about medicines and other interventions to the public through the media and other means.