



Reorienting European policy on medicines for human use

For a policy on medicines that puts patients first

Knowing which are the active ingredients of a drug, being informed on the added therapeutic value of a new drug, benefiting from a compassionate use programme when it is vital, reporting an adverse effect, contributing to transparency of agencies by joining their board, these are a few of patients needs. Time for listening to pharmaceutical industry only is over. Patients should be taken into account.

Ultimately medicines are used and paid for by patients/citizens/national insurance contributors.

The revision of the European Directive and Regulation on medicines should, quite rightly, provide the opportunity to place the emphasis on the needs of patients and of European citizens in general.

Information is key to making the best possible use of medicines. The days when doctors and pharmacists spoke Latin and prescribed "secret remedies" whose properties were known only to them are long over. Today, patients have the right to know what decisions are taken about their health and to be told about the expected effects of their treatments.

This fundamental right includes being informed of the precise active ingredients of medicines. In addition to the drug's brand name, its International Nonproprietary Name (INN), i.e. its scientific name, must be stated on the packaging and in advertisements.

Patients are also entitled to know whether the medicines they are using really are the most suitable for their particular condition. It is always astonishing to discover that many new medicines are sold without having been compared to the most appropriate drugs for the

same disease already available on the market.

Health authorities must be able to supply information on the "added therapeutic value" of new medicines, i.e. comparative data on medicines, or on the lack of such data if that is the case. This information can only be obtained if the appropriate clinical trials are carried out. And it is this reliable information that patients require, not information put out by the pharmaceutical companies and designed for promotional purposes.

Representation of civil society on the boards of medicines agencies. Each day European and national medicines agencies take decisions that concern patients' health: the evaluation of new medicines and their marketing authorisation; monitoring adverse effects and withdrawing drugs from the market for safety reasons; the production of information for health professionals and patients, etc.

Given that the pharmaceutical industry represents huge financial stakes, it is essential for the decisions taken by the agencies to be transparent, and for this duty of transparency to be enshrined in law. Transparency must also be the watchword in the day-to-day running of the agencies. It is necessary to have representa-

tives of civil society on the agencies' management boards to remind these institutions at all times of their duty to protect the public interest.

Patients, healthcare professionals and social protection systems must be represented on these boards.

Compassionate use for patients in a therapeutic impasse. Patients with terminal diseases in a therapeutic impasse, i.e. those for whom there are no effective existing treatments, must have access to promising medicines which have not yet been authorised for sale. This principle is readily acknowledged, but it will only become practice if the national authorities are forced to set up compassionate use programmes whenever necessary. It is therefore a question of putting in place the application procedures for starting such a programme at the request of health professionals or patient groups, and of earmarking the necessary funding.

Direct reporting of adverse effects. Doctors and pharmacists can inform the national pharmacovigilance system of adverse or unusual effects they have observed, in particular where new medicines are concerned. This system is not ideal, however, because not all health professionals are stron-

gly motivated to report adverse effects, and because they do not necessarily place the same degree of importance on some adverse effects as the patients themselves. And so it is essential to allow patients to report to the public pharmacovigilance system directly any adverse effects. They could do so by filling up a form available from community surgeries and pharmacies.

It is now recognized that patients have a role to play in the smooth running of health care systems. But the European legislation on medicines currently under revision still does not pay them enough attention. Patients have specific demands and now is time to listen to them.

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