## Reorienting European policy on medicines for human use

# Information on "added therapeutic value" must be publicly accessible

**New drugs appearing on the market should have been compared to available treatments for the same condition. Information on "added therapeutic value" is essential for patients, health care providers and those who pay for medicines.**

There are numerous medicines on the market today, but they do not all have the same risk-benefit balance. Comparing them in clinical trials makes it possible to assess their respective "added therapeutic value".

**"New drug" does not necessarily mean "therapeutic advance".** Some older medicines have not been superseded by more recent ones. This is true, for example, of *paracetamol*, which remains the most effective analgesic for light to moderate pain, the one which has the best risk-benefit balance, even thought it is more than 100 years old. The same also applies to thiazide diuretics, which are now proved to be the best first-line antihypertensive drugs. There are numerous diseases or symptoms for which the most effective medicines are 10, 20, or even 50 years old.

Conversely, many supposedly "innovative" new drugs do not offer patients any real improvements.

**Free trade and public health do not necessarily go hand in hand.** How is it possible for new medicinal products that do not offer patients any tangible improvements to be put on the market? Simply because the principle of free trade applies to the pharmaceuticals sector: currently, the health authorities cannot legally refuse to authorise the sale of a medicinal product which is more or less "as good as" a product already on the market.

Naturally, the pharmaceutical companies support this principle according to which new medicines are not required to be an "improvement" on existing ones. They use it as an argument against new medicines being systematically compared to older medicines prescribed for the same diseases.

**Patients, health professionals and social protection bodies want to be able to make the best choices.** Health professionals, patients and the public at large who use and pay for medicines need to know whether a new drug is or is not an improvement on existing treatments, in terms of benefits, risks or even convenience.

Furthermore, the resources of mutual insurance systems are being stretched by the proliferation of increasingly expensive medicines, often to the detriment of other necessary medical or social expenses. All these factors make a strong case for providing data on the added therapeutic value of new medicines when they are authorised and marketed. And to assess this added therapeutic value, appropriate comparative clinical trials must be carried out.

Once a drug has been authorised for sale, the five-year re-evaluation should be seen as a valuable second opportunity to analyse the available data thoroughly, taking into account its use in real situations. Useful up – dated information on the drug's risk-benefit balance and on its relative added therapeutic value could then be made public.

**Amendments for the best use of medicines.** The Medicines in Europe Forum supports several amendments seeking to make data on the added therapeutic value of new medicinal products public at the time of their initial authorisation for sale and after the five-year re-evaluation.

It is a question of enabling health professionals and patients to be fully informed about the drugs they are using, in particular new ones. Useful information on a drug comes from trials comparing it with other treatments already available.

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