Looking back on New Drugs 2006 and revised drug ratings

Reconsideration of the balance between efficacy and side-effects of newly introduced drugs shows that for most of them, the assessment given in 2006 has remained unchanged or has to be downgraded. All the money and efforts that went into their development and production have not benefited patients at all.

This new survey comes to the same conclusion as the previous annual surveys, namely that at the time when a new drug is introduced, relatively little is known about its efficacy and side-effects, so that caution needs to be exercised when prescribing such new drugs. Ten years after their introduction, remarkably little long-term research has been conducted into these drugs. Nevertheless, the indications for four of these drugs have been extended, based on very limited research. The relevant authorities can rightly be reproached for not requiring such research as a precondition for registration. For a number of drugs, some evidence has emerged for (albeit rare) serious side-effects, and these drugs should be avoided at least for relatively innocent and non-life-threatening conditions. Another striking aspect is that EMA has not decided to withdraw the market authorisation for strontium ranelate, in view of its serious side-effects.

It is also striking that there have been relatively few publications about side-effects. For some drugs, the number of reports to the Dutch adverse effects reporting centre Lareb is also low. It is not just the pharmaceutical industry and the reporting centres which are to blame for this, however. Care providers could play a far more proactive role in this respect, by actively following patients using new drugs and reporting any side-effects to reporting centres like Lareb (www.lareb.nl).

The number of drugs given market authorisation on the basis of a shortened and simplified registration procedure is expected to rise considerably over the next few years. In such procedures, the manufacturer is obliged to supplement the missing studies after the drug has already been admitted to the market. It is to be hoped that the trend towards diminishing post-marketing research reported in this Gebu article will be reversed by this obligation. If not, the percentage of drugs which have been authorised without sufficient data on efficacy and side-effects will only rise. The exposure of more and more patients to such drugs as guinea pigs is an undesirable development.

Four of the six drugs discussed in the article are mentioned in Dutch guidelines. It is good to see that none of these are being recommended as the treatment of first choice, as the authors of these guidelines rightly concluded that their benefits do not outweigh the disadvantages. It may be concluded that none of the new drugs discussed in Gebu in 2006 has since then proved to offer added value. It is high time to revise the current views on drug development, drastically reducing the role of the pharmaceutical industry and expanding the role of universities and university-affiliated research centres. Public institutions ought to take the lead, so that the influence of market forces can be reduced. Unfortunately, we will have to wait another year to find a new drug that has proved its value after ten years.

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*The literature refers to the Dutch text*