Anytime patients pick up a drug from a pharmacy, they are also given an official package leaflet. The question is whether this procedure fulfils the purpose for which it was once introduced, viz. to promote the correct use of drugs. If a package leaflet is to be effective in terms of optimising the efficacy and minimising the risks of a drug, it will need to satisfy certain conditions. First of all, the leaflet must be shown to be sufficiently readable and comprehensible. It turns out, however, that the methods recommended by the regulatory authorities to assess this feature certain obstacles that make it difficult to meet this requirement.

The obstacles inherent in the current legislation and guidelines make it likely that many patients will find it difficult to understand the leaflets. The examples of unintelligible information given in the article reinforce the notion that the readability tests applied to these leaflets fail to achieve their purpose. The drive towards improving readability and comprehensibility is however impeded by the fact that the guidelines and templates provided by the regulatory authorities are as yet far from satisfactory and actually stand in the way of readable package leaflets. Progress is further hampered by the fact that the results of the readability tests are not published. In addition, unnecessarily elaborate tests, which attach greater importance to quantitative than qualitative requirements, do not contribute to greater readability and comprehensibility.

Research into the effectiveness of package leaflets has been scarce and has limited itself to the effect of the verbal and/or numerical presentation of side-effects. Research into attitudes and behaviour provides clues as to possible and already implemented improvements, but does not offer concrete leads. There has been no research using the hard outcome measure of health effects, and such research is not easily realised.

Package leaflets offer ample information about risks and side-effects of a drug, whereas its efficacy is usually only very briefly presented. It turns out that the information as currently presented in the leaflets results in patients greatly overestimating the risk of experiencing certain side-effects. Hence, the leaflet appears to deter patients rather than supporting drug treatment. It has never been studied whether patients discontinue certain drugs, or do not even start using them, because of the information presented in the package leaflet.

No research has been published on the effectiveness of package leaflets in terms of improving the efficacy and reducing the risks of drugs. Randomised trials involving a fully non-informed control group is impossible because of the unrestricted availability of information and the many ethical and legal objections to not providing patients with information. This does not mean that giving patients package leaflets is useless. Without such ‘instructions for use’, drugs will be dangerous and potentially even fatal. It will be clear, however, that expert advice could produce considerable improvement as regards patient education and information design. As it is, the legal aspects (meeting the requirements stated in the law) and the manufacturers’ desire to cover themselves against liability appear to prevail over the Dutch Medicine Evaluation Board’s stated objective of these leaflets, to ‘promote the responsible use of medicines.’

References*


17. Young A, Tordoff J, Smith A. Regulatory agencies’ recommendations for medicine information leaflets: are they in line with research findings? Res Soc Admin Pharm 2017; xxxx


*The literature refers to the Dutch text*