Prescrire International Editorial

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Being pragmatic

To determine what it will offer in a given clinical situation, three aspects of a drug must be examined: its efficacy, its adverse effects and how easy it is to use in the reality of everyday health care. A new pharmaceutical product that is just as effective and safe as existing alternatives can still represent a therapeutic advance because it is easier to use in a particular clinical situation. On the other hand, if it is less convenient, it amounts to a step backwards.

For example, an oral or injectable sedative can be difficult to administer to an agitated, uncooperative patient. A more satisfactory alternative is needed.

The respiratory route is an attractive possibility in theory. But in practice, such a product would also have to be designed to truly suit the often challenging conditions under which it will be used. That is not the case for *loxapine* (Adasuve°), a neuroleptic authorised as an oral inhalation powder for acute agitation (pages 118-119).

Despite its novel delivery device, administration of the drug requires the patient's cooperation and can provoke bronchospasm, a particularly unfortunate adverse effect when the objective of treatment is to calm an agitated patient. In the end, the European marketing authorisation was only granted for cooperative patients, who are therefore capable of voluntarily taking a drug orally or of agreeing to an injection, without this increased risk of bronchospasm.

Drug companies and regulators that are concerned about providing drugs that represent real progress in terms of ease of use must take a very pragmatic approach to their design and evaluation, focusing on the most challenging conditions under which they will be used.

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