

Translated from **Rev Prescrire** April 2012; 32 (342): 247

Common sense

The clinical development of a new drug takes time (several years) and considerable financial and human resources (healthy volunteers, patients, healthcare professionals).

Common sense dictates that this investment is only worthwhile if it has a reasonable chance of producing a drug that is both useful to the patients concerned, in terms of its harm-benefit balance, and convenient to use, taking into account the alternatives that are already on the market.

The neuroleptic drug *asenapine* (see page 229 of this issue) is a case in point. Human studies soon showed that *asenapine* is not absorbed by the gastrointestinal tract, and that a sublingual form would have to be developed for oral administration. In practice however, sublingual tablets are difficult to take correctly, especially for psychotic patients in

distress. Oral liquid preparations or even injectable forms are preferable for treatment of these patients, and neuroleptics had long been available in these forms when the first clinical trials of *asenapine* were initiated.

Thousands of patients participated in these trials, which confirmed the unremarkable efficacy of this drug compared to existing neuroleptics, along with additional adverse effects and practical drawbacks associated with its pharmaceutical form. The result of the stubborn persistence on the part of the trial sponsors was a disappointing waste of time and resources. Yet this could have been avoided with a modicum of experience in the reality of patient care and the use of common sense, focusing first and foremost on patients' interests.

Prescrire