Translated from *Rev Prescrire* May 2011; 31 (331): 321

Freedom to inform

In 2009, contrary to the opinions held by the company and the European Medicines Agency, *Prescrire* concluded that the evidence supporting the efficacy of topical *tacrolimus* for relapse prevention in some forms of eczema was too weak in view of its known adverse effects. Astellas Pharma, the marketing authorisation holder, instituted legal proceedings intended to impose a gag order on *Prescrire*, arguing that marketing authorisation constitutes proof of a positive harm-benefit balance, and that challenging this official endorsement amounts to "denigration" (see page 191 of this issue).

What would patients think if independent analysts could be prosecuted for providing sound and balanced information to their health care providers? Is it conceivable that they would want their healthcare providers to prescribe an eczema treatment without being fully informed of its benefits and harms? Could patients possibly imagine that *Prescrire's* intention was simply to disparage *tacrolimus* rather than to protect their health?

In 2011, Astellas Pharma's lawsuit was thrown out by the Paris High Court. The judges pointed out that *Prescrire* had the freedom to inform and to criticise, provided it conducted a thorough analysis of the relevant clinical data. This includes the freedom to criticise marketing authorisation decisions. Similarly, in 2010, the French Supreme Court ruled that a primary health insurer had the right to provide physicians with information on a product that was not necessarily limited to the terms of the marketing authorisation.

Patients should welcome these legal rulings, which ensure that their physicians will have access to the information necessary to provide high-quality care. Physicians are thus in a position to provide information to their patients and to choose, along with them, the best available treatment option.

Physicians will have access to independent information, that has not been cherry-picked by drug companies or that is based solely on the conclusions of regulatory agencies. They will therefore continue to be informed when a drug has a negative harm-benefit balance, even if regulators have given their approval for its market release.

The *Prescrire* team will continue to conduct rigorous, totally independent reviews of drug evaluation data, and to inform health professionals of its conclusions. The objective is to ensure high quality healthcare, in which patients' well-being is the first priority.

Prescrire