Prescrire International Editorial

Translated from ***Rev Prescrire*** **February 2012; 32 (340): 81**

Unfinished business

In 2011, France passed a new law changing many aspects of the regulation of the health products market. This first step toward much-needed reforms is to be commended. Once due credit has been given, of course, to the courage and determination of the doctor who exposed the Mediator° scandal: Irène Frachon.

But this reform does not go far enough. Yes, changes are already evident in the way the French drug regulatory agency operates; but only time will tell whether there is real progress. Yes, the handling of conflicts of interest should improve; but there is no guarantee that clinical evaluations will be free from the influence of drug companies. Yes, France's drug regulatory agency will be able to use this law to request more postmarketing clinical trials; but there have been no changes to the situation prior to marketing authorisation: it will still be possible to authorise drugs that have never been compared to the existing standard treatments.

Some point to France's membership in the European Union as an obstacle to farther-reaching measures. France's representatives in Europe therefore need to push tenaciously and over the long term for the changes that are needed in the legal framework and the ways of working.

The new law has the feel of unfinished business. Partly because the bill has only taken into account a small fraction of the recommendations made by the parliamentary missions, of the reports from France's general inspectorate of social affairs (IGAS) and other national conferences on medicines policy, not to mention *Prescrire*'s 57 proposals. And partly because the French Parliament has refused any compromise with the Senate. In particular, Parliament rejected measures voted by the Senate that would have allowed better protection for the victims of adverse effects (notably class action suits).

Another missed opportunity: there is no mention of the urgent need to improve initial and continuing education of health professionals regarding drugs and patient safety.

France has a very real problem with medicines in general: it is one of the highest consumers of medicines in the world, and hundreds of thousands of its citizens suffer serious adverse drug effects every year. This problem will not be solved by France's new law on medicines.

Much remains to be done. But the debate on medicines that was opened in 2011 in France shows that other necessary advances are achievable through inclusive discussion and a focus on real progress and patient protection.

Prescrire

Downloaded from english.prescrire.org on 12/10/2026
Copyright(c)Prescrire. For personal use only.