drugs is easily missed. *Prescrire* carefully reads all of the changes made to summaries of product characteristics (SPCs), as well as all the published minutes of the meetings of regulatory agency committees, in order to identify any new information that would be useful in healthcare practice or for patient protection.

A few notable examples unearthed in 2012 are: hepatic risks and hallucinations added to the SPC for *agomelatine* (*Rev Prescrire* n° 348); optic neuropathy reported in the EMA's "Procedural steps taken and scientific information after the authorisation" for *bortezomib* (*Rev Prescrire* n° 349); serious, including fatal, skin lesions added to the SPC for *febuxostat* (*Rev Prescrire* n° 347); abuse and addiction associated with *methylphenidate*, an amphetamine-like stimulant marketed for attention-deficit hyperactivity disorder, reported in the minutes of a French drug regulatory agency (ANSM) meeting (*Rev Prescrire* n° 344); deaths and cutaneous and cardiac risks associated with *midodrine*, reported in the minutes of an ANSM meeting (*Rev Prescrire* n° 343); and occasionally serious allergic reactions added to the SPC for *Saccharomyces boulardii*, a probiotic taken for diarrhoea (*Rev Prescrire* n° 348).

Advertising and marketing: the authorities are too lenient

Drug companies use various strategies to encourage drug consumption. Healthcare professionals and patients cannot rely on the information they provide, given their major conflicts of interest.

In 2012, we exposed several tactics used by pharmaceutical companies that place profits above patients' needs: proposing a pharmacological solution to all health problems (medicalisation of life and disease mongering); using opinion leaders to influence healthcare professionals; and funding "training" for medical students (*Rev Prescrire* n° 339, 341 and 349).

Some companies have engaged in truly harmful activities, for example: Roche concealed adverse effects, particularly in patients who had died; and GlaxoSmithKline conducted misleading promotional campaigns encouraging off-label use of its drugs (*Rev Prescrire* n° 349).

In France, in 2012, before prior approval was required for drug advertising aimed at health professionals, 7 advertisements were banned for serious violations: unethical extension of indications, exaggeration of efficacy, or promotion of off-label use. One of these ads promoted the use of the nonsteroidal anti-inflammatory drug *flurbiprofen* during pregnancy, which could harm the unborn child (*Rev Prescrire* n° 340, 342 and 347).

Drug advertising is bad for health, yet the authorities continue to refuse to ban it. In France, in 2012, a small breakthrough was made by requiring prior authorisation of drug advertisements aimed at health professionals (*Rev Prescrire* n° 347). On the other hand, governmental agencies missed an opportunity to put an end to direct-to-consumer advertising of vaccines (*Rev Prescrire* n° 350).

All too often, the drug industry's interests continue to take precedence over those of patients and public health.

Putting patients' interests first

In 2012, yet again, any true therapeutic advances were minimal, and did not reverse the trend observed in previous years, leading to the 2011 Prescrire Drug Awards ceremony in which not a single medication was granted an award (*Prescrire Int* n° 125).

The pharmaceutical market is still overrun with dangerous drugs: we have drawn up a list, based on 3 years of *Prescrire* reviews, that includes about 80 drugs that should not be prescribed, without waiting for regulatory action (see pages 108-111). The health authorities do not fully appreciate the dangers of these drugs. Regulatory agencies can no longer afford to simply inform patients of the risks or to procrastinate: it is high time these drugs were withdrawn from the market.

Let's hope that 2013 will be the year of major advances in patient protection.

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Drug policy: let's maintain pressure on regulatory authorities

France's recent "drug safety" law, developed in response to the Mediator° (*benfluorex*) disaster, was supposed to ensure that greater consideration would be given to the dangers of drugs (*Prescrire Int* n° 127). In practice, the law passed at the end of 2011 fell well short of the initial recommendations.

Some progress in transparency. The French health products agency's (ANSM) resolve to oversee and regulate medicinal products has remained timid, although progress initiated at the end of 2011 with the publication of the agendas and detailed minutes of its committees' meetings continued in 2012.

Prescrire has also noted that the French National Authority for Health (HAS) provides slightly more information on its website, having published 2 draft opinions on drugs for which the pharmaceutical company withdrew its request for reimbursement (*Rev Prescrire* n° 350).

However, experience has shown that some opacity remains.

No bold political decisions in 2012. Commitment has faded since policymakers took a bold stance during debates on France's "drug safety" bill. No significant progress was made in 2012.

A number of measures are still required if drug policy is to better serve the interests of patients and all citizens:

– a significant increase in the funding of independent clinical research, free from the influence of the pharmaceutical industry (*Prescrire Int* n° 129);
– a body of independent experts with no vested interests;
– changes in European legislation, making it mandatory to compare new drugs with standard treatments to determine the therapeutic advance they represent (*Rev Prescrire* n° 342);
– establishment of an evidence-based hierarchy of treatment options;
– high-quality, safe drug packaging, to prevent medication errors (see the May 2013 issue);
– greater transparency on the part of health authorities, including access to clinical trial data and pharmacovigilance data;
– funding for continuing education for healthcare professionals, free from the influence of the pharmaceutical industry;
– the exclusion of commercial interests from all healthcare and educational establishments;
– improved detection and compensation of victims of the adverse drug effects.

Consider patients first. Given the weaknesses in drug regulation in both France and the European Union, it is up to healthcare professionals to be critical and to always put patients' interests first.

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