– some products based on *meprobamate*, used for more than 40 years in alcohol withdrawal, and the fixed-dose combination of *meprobamate* + *aceprometazine*, used for nearly 50 years in insomnia (*Prescrire Int* n° 123);
– a fixed-dose combination powder (Paps°) of *salicylic acid* + terpenes (*camphor, levomenthol, lavender essential oil*) + *bismuth* + *zinc* + *boric acid*, marketed for nearly 50 years for pruritus (*Rev Prescrire* n° 338);
– products based on *pioglitazone*, an antidiabetic drug (withdrawn in France but maintained by the European Commission on the advice of the EMA) (*Rev Prescrire* n° 335).

Other welcome withdrawals included:
– combinations based on *dextropropoxyphene*, marketed for more than 45 years for pain relief: withdrawn from the market following a European reassessment (*Rev Prescrire* n° 327, n° 328);
– *celecoxib* in familial adenomatous polyposis: European marketing authorisation was withdrawn because the company failed to provide supporting data (*Prescrire Int* n° 121);
– *becaplermin* (*Rev Prescrire* n° 335), *drotrecogin alfa* (*Rev Prescrire* n° 338) and *sitaxentan* (*Rev Prescrire* n° 328), all withdrawn at the request of the drug companies, not the regulatory agencies.

Some decisions supported patients' interests. Some position statements and decisions taken by drug regulatory agencies' in 2011 are worthy of note:
– the French regulatory agency and EMA refused to authorise over-the-counter use of *sumatriptan* in migraine (*Prescrire Int* n° 123);
– coherent changes were made to the indications and dosages of *penicillins M* (*cloxacillin* and *oxacillin*), useful older drugs, following reassessment by the French agency (*Rev Prescrire* n° 336).

However, other decisions represented simple half-measures, such as the decision by the French agency to restrict the use of antihistamine antitussives in children less than 2 years old, even though these products have a negative harm-benefit balance in older children and adults. It would have been better to simply withdraw these products from the market (*Rev Prescrire* n° 329).

Drug regulatory agencies still providing too little information on adverse effects. Information provided by regulatory agencies can help healthcare professionals manage their drug lists and choose the most appropriate drug for each patient. In 2011, the French agency made an effort to improve the quality of this information. For example:
– oleocalcic liniment: risk of burns when prepared at home by patients (*Rev Prescrire* n° 328);
– *dronedarone*: liver damage and heart problems (*Prescrire Int* n° 120);
– *somatropin*: increased mortality due to cerebrovascular disorders and bone tumours (*Prescrire Int* n° 117);
– *strontium*: numerous cardiovascular and cutaneous adverse effects, etc. (*Prescrire Int* n° 117);
– *dasatinib*: pulmonary arterial hypertension (*Prescrire Int* n° 120).

However, other important information is buried in the summaries of product characteristics (SPCs), patient leaflets, and the EMA's "steps taken after authorisation" or "assessment reports":
– *tianeptine*: cutaneous disorders were added to the SPC, but they are not all mentioned in the 2011 patient leaflet (*Rev Prescrire* n° 337);
– *natalizumab*: data on infections (including progressive multifocal leukoencephalopathy) and hypersensitivity were released in a report from the French Pharmacovigilance Committee (*Prescrire Int* n° 122);
– *thalidomide*: data on hearing loss were provided in "steps taken" (*Prescrire Int* n° 124).

Aggressive drug promotion

Faced with the pervasiveness of drug promotion by pharmaceutical companies and weak regulations, healthcare professionals and patients must remain vigilant.

Do not confuse advertising and information. Healthcare professionals and patients must keep in mind that drug companies' advertising messages concerning their products should not be considered reliable sources of information.

Efficacy is stressed while adverse effects are downplayed or not mentioned at all: for example, *varenicline* in smoking cessation (*Rev Prescrire* n° 336 inside back cover), the fixed-dose combination of *tramadol* + *paracetamol* for pain (*Rev Prescrire* n° 329 inside back cover and n° 337 inside back cover), and *ketoprofen* gel for rheumatic pain (*Rev Prescrire* n° 328 inside back cover).

Pharmaceutical industry obsession with drug promotion. Drug companies exploit every possible opportunity to promote their products, directly or indirectly, by various means, including:
– patient management software (*Rev Prescrire* n° 336);
– healthcare professional "training" (*Rev Prescrire* n° 331);
– gifts to healthcare professionals. It has been shown that even small gifts "of negligible value" elicit reciprocity on the part of the recipient who is often unaware of their influence (*Prescrire Int* n° 122);
– drug companies have been known to send healthcare professionals falsi- ▶▶

Questioning French drug policy: a few timid steps taken in 2011

In 2011, the rationale for French drug policy was challenged by the Mediator° disaster (*Prescrire Int* n° 121).

In March 2011, *Prescrire* published 57 proposals on its website (english.prescrire.org), based on evidence accumulated over the years, aimed at preventing similar disasters in future and at refocusing national drug policy on public health and patients' real needs (*Prescrire Int* n° 116, 121 and 123).

A new law on human medicines was passed in France on 19 December 2011.

Some of its measures will serve patients' interests:
– better management of conflicts of interest within government agencies;
– more transparent reporting of committee meetings;
– stricter regulation of off-label prescription;
– stricter regulation of medical devices.

However, several important measures were left out:
– development of clinical research more independent of drug companies;
– public access to pharmacovigilance databases, as in countries such as Canada, the United States, the Netherlands and the United Kingdom (*Rev Prescrire* n° 337 - see this issue page 99);
– requirement to compare new drugs with a standard treatment before marketing authorisation or reimbursement status can be granted;
– measures to promote more convenient treatment and safer packaging (see in a coming issue);
– Better initial and continuing education of healthcare professionals in drug therapy.