In 2006 we assessed 782 drugs or indications in our French-language sister journal *la revue Prescrire*, compared to 600 in 2005. The difference was mainly due to the larger number of new indications and generic equivalents in 2006.

Still many bogus new products

In France, many of the new drugs marketed in 2006 were in fact false innovations, reflecting the loss of R&D momentum in the pharmaceutical sector.

New from the old. The 50 new commercial products we examined in 2006 (excluding generics and line extensions) included:
– Eight substances that had already been marketed; the new indications were generally insignificant. These products included: azelaic acid (*la revue Prescrire* n° 268); nicotinic acid SR (*la revue Prescrire* n° 275); diclofenac (*la revue Prescrire* n° 275); single-dose oral morphine (*la revue Prescrire* n° 275); and testosterone (undecanoate) (*la revue Prescrire* n° 274). In three cases the new indication had a degree of specificity: eflornithine in hirsutism (*Prescrire International* n° 83); flurbiprofen lozenges for throat pain (*Prescrire International* n° 87) (see below); and ropinirole for restless legs syndrome *Prescrire International* n° 85) (see below);
– Four old products, now developed for the treatment of rare diseases, giving them orphan drug status, and thus providing the manufacturers with a range of financial advantages: injectable ibuprofen (*Prescrire International* n° 85); inhaled iloprost (*Prescrire International* n° 83); levodopa + carbidopa duodenal gel (*la revue Prescrire* n° 277); and sildenafil tablets in pulmonary hypertension (*Prescrire International* n° 86);
– Six new substances very closely related to drugs already on the market (me-toos), providing no tangible therapeutic advantage for patients: erlotinib (a product close to gefitinib) (*Prescrire International* n° 83); insulin glulisin (the third fast-acting insulin analogue) (*la revue Prescrire* n° 272); insulin detemir (the second long-acting insulin analogue) (*Prescrire International* n° 85); tiotropium (the third atropinic agent, following ipratropium and oxitropium) for use in chronic obstructive pulmonary disease (COPD) (*Prescrire International* n° 84); rasagiline (the second type B MAOI for Parkinson's disease, after selegiline) (*la revue Prescrire* n° 273); and pegfilgrastim (pegylated filgrastim) (*la revue Prescrire* n° 273);
– Nine combination products containing active ingredients that were already marketed individually, mainly for cardiovascular indications.

In total, truly innovative substances ►►

Drug regulations: some advances in 2006, others eagerly awaited in 2007

Some welcome changes were made to the regulatory framework in 2006, but many others were delayed or postponed.

The French regulatory agency is starting to take its transparency obligations seriously. The EU Directive on human medicines places stringent demands on drug regulatory agencies as far as transparency and access to data are concerned.

A Directive becomes legally binding after the transposition deadline, and all Member States are required to ensure that their national legislation conforms to the Directive.

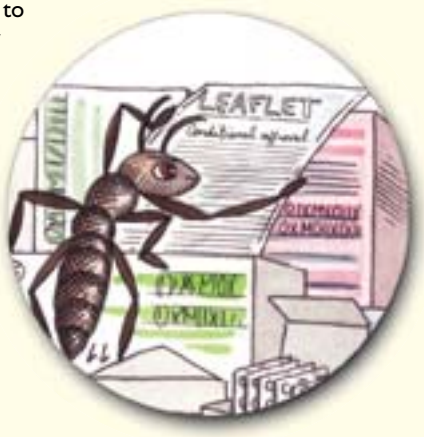
Signs of greater transparency appeared on the French agency's website, which last year posted the internal rules of the marketing authorisation committee, as well as minutes of meetings of the marketing authorisation committee and the national pharmacovigilance committee.

However, many data are still not available online: on 4 January 2007, only 5608 of the 17 517 existing SPCs were available online, together with 47 public assessment reports and 9 minutes of meetings. No reports were available for the second half of 2006.

As for the conflicts of interest of the experts sitting on the different agency committees, more transparency and more stringent rules are needed.

Conditional European marketing authorisation: ensure strict application of the Regulation. In March 2006, a Regulation dealing with "conditional" European drug approvals was adopted.

Conditional approval allows more rapid access to potentially useful drugs, but also leaves the door open to products with little therapeutic value. Transparency obligations must be respected, and conditional market approvals must not be allowed to simply become a way of speeding the clinical assessment of a new drug.



French transposition of the Directive on human medicines: expectations and dangers. European Directive 2004/27/EC dramatically modified the European legislative framework for human medicines. This Directive should have been transposed into French law before 30 October 2005, but, at the time of writing, the transposition law is not yet completed.

Some of the provisions of the Directive support patients' interests and are eagerly awaited; they include: Braille labelling on drug packages; prior assessment of the wording of patient leaflets by patient representatives. Other provisions on transparency, marketing authorisation, generics, etc. have already been transposed.

It should be noted that the transposition draft introduced a provision not mentioned in the Directive and created only to serve the commercial interests of drug companies: it deals with "compliance support programmes" run by drug companies (*Prescrire International* n° 83 and 87). The principal objective of these programmes is to retain clients for drugs that are losing market share: in other words these programmes have more to do with drug promotion than with healthcare and should be forbidden.

This attempt has been rejected thanks to lobbying by French members of the Medicines in Europe Forum. But the French health minister has already announced a new proposal on compliance programme for Autumn 2007.

Citizens, patients and healthcare professionals must work together to ensure that all the measures designed to ensure high-quality healthcare are fully implemented.