

In the wake of the Mediator° scandal: some progress in France, but apathy at the European level

The aftermath of the Mediator° disaster and the serious regulatory shortcomings it revealed led the French authorities to make some improvements to their procedures and decisions in 2011 (*Prescrire Int* n° 121). For example:

- The French drug regulatory agency finally made a real effort to be more transparent: the working sessions of the marketing authorisation committee are now described in detailed reports, albeit several months later; some (but not all) discussions are now filmed and posted online; and the agendas of the marketing authorisation committee are now made public. Previously, reports of this committee's activities were scant, and none of its debates was filmed for public viewing;
- the French agency triggered reassessment of several drugs at the European level, including *pholcodine*, *pioglitazone* (alone or combined with *metformin*), and *trimetazidine*;
- the French agency decided to withdraw several drugs with negative harm-benefit balances (see inset page 108);
- the French authorities are taking more notice of recommendations of the Transparency Committee (which assesses the medical benefits of new drugs and advises on drug reimbursement) to stop reimbursing several drugs rated as providing inadequate medical benefit to patients, some of which have been on the market for several years.

In contrast, the European authorities have yet to take action on these points:

- the opacity of pharmacovigilance data persists: for example, information was withheld on the risks of bladder cancer associated with *pioglitazone* (*Prescrire Int* n° 123);
- doubts regarding drug safety still continue to benefit drug company profitability rather than patients' interests: some drugs were kept on the market despite their established harms, including *dronedarone*, *nimesulide*, *pioglitazone*,

pholcodine and *varenicline* (see inset page 108);

- in the public consultation launched by the European Medicines Agency (EMA), posted online in late 2010, the Agency proposed to make head-to-head comparisons with a standard drug the exception in premarketing clinical trials, meaning that placebo-controlled trials would become the rule (*Prescrire Int* n° 121);
- the European Commission left signal detection and the interpretation of post-marketing surveillance data in the hands of drug companies. These are both key elements of drug safety (isdbweb.org);
- the European Commission continues to insist on removing barriers to direct-to-consumer advertising by drug companies for prescription-only drugs. Following the public outcry in late 2010, the Commission was forced to revise its proposals to allow direct-to-public advertising of prescription drugs, disguised as "information". However, the amended proposals published in October 2011 still leave the door open to this type of advertising, particularly the proposed legalisation of reminder advertising (a) (english.prescrire.org).

The public must encourage authorities to focus more on patient safety, through actions such as those conducted by the patient group *Amalyste* (victims of *Lyell* and *Stevens-Johnson* syndrome) and *Act Up* (people living with HIV/AIDS), and member associations of the Medicines in Europe Forum (b) ("Prescrire Prize", prescrire.org).

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a- *Reminder advertising is a marketing practice which aims to familiarise the public with a brand name by using every opportunity to mention the name of the product, including using images of the brand and building an emotional connection with the brand.*

b- *Founded in March 2002, with more than 60 member organisations in 12 European Union member states, the Medicines in Europe Forum is composed of 4 major groups of healthcare stakeholders: patient groups, family and consumer organisations, health insurers, and healthcare professionals (prescrire.org)*

- ▶ fied emails and letters from patients thanking their doctors for having prescribed one of their drugs (*Rev Prescrire* n° 330);

- "disease mongering", particularly in the field of psychiatry (*Prescrire Int* n° 112);
- funding of patient groups. According to a survey by Health Action International (HAI), an international network of organisations and citizens striving,

among other things, to promote rational use of healthcare and medicines, most patient groups funded by pharmaceutical companies support direct provision of "information" by drug companies (*Prescrire Int* n° 122);

- harassment and vilification of scientists by the Danish Association of the Pharmaceutical Industry (*Rev Prescrire* n° 328);
- etc.

Regulation of advertising: doubtful effectiveness. Few unethical ads sanctioned in France. Few advertisements aimed at healthcare professionals were banned in France in 2011, according to the Official Journal (*Journal Officiel*). As in previous years, the violations were mainly serious, including unethical broadening of indications, promotion of off-label use (including *mequitazine* during pregnancy), exaggeration of effectiveness (*Rev Prescrire* n° 333 and 340). Formal notices to modify these ads are not made public in France. Healthcare professionals were therefore unaware of having been exposed to misleading advertisements.

In Switzerland, despite more stringent regulations requiring that all drug advertisements should be evidence-based, the situation is appalling: half of the claims are not backed up by the cited references, or are based on biased references (*Prescrire Int* n° 117).

Support the new focus on patients' interests

In France, the year 2011 was characterised by the lack of major breakthroughs in new drugs or new indications, but there were some welcome decisions aimed at improving patient safety in the wake of the Mediator° disaster, such as market withdrawal of drugs that had more harms than benefits. There was also a trend towards a culture of transparency, and other changes in drug policy, the practical impact and sustainability of which remain to be seen. At the European level, apathy prevailed and no new changes of significance were made to protect patients' interests.

Drug companies must focus on producing high-quality pharmaceuticals (*Prescrire Int* n° 124) and ensuring an uninterrupted supply of products with proven clinical value, such as *spiramycin* oral suspension, which was no longer marketed in France in 2011, and sheep antidigitalin antibodies, that are too often out of stock and are replaced by various brand names and dosages (*Rev Prescrire* n° 333).

A more general overhaul is needed: healthcare professionals must sever their links with drug companies (*Rev Prescrire* n° 330); patients must learn not to rely solely on medications (*Prescrire Int* n° 122); and all those concerned must choose reliable sources of information.

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