community are "sacrificed" for the public good.

National compensation. In the case of serious adverse drug reactions, it is high time this responsibility translated into an obligation for compensation.

It should also be pointed out that victims of serious adverse drug reactions cannot obtain compensation through the courts if the adverse effect in question was mentioned in the patient leaflet, even if the risk is not fully understood (how many people are aware of the severity of Lyell or Stevens-Johnson syndromes?). In practice, for patients who experienced serious adverse drug reactions before 2001 in France, this means a lack of compensation.

Conclusion

Drug therapy currently resembles a gigantic game of Russian roulette. The "risk-benefit ratio" – the concept on which the current system is based – creates a situation in which society and drug companies reap most of the benefit while leaving a handful of victims to shoulder the risks.

How can this situation be remedied? Regulatory authorities must create a level playing field in which the community fully assumes its responsibility for the consequences of marketing a high-risk drug. This implies acknowledgement of the existence of the risk; an obligation to provide the means necessary to reduce drug-related illness (means compatible with the importance of the public health implications); an obligation to conduct research on adverse reactions to high-risk drugs; and proper management of the consequences when harmful effects occur, including financial compensation. These measures are the minimum that one is entitled to expect from a responsible state.

We, an association of victims of very serious drug-related accidents, are determined to participate in this debate. We recommend a fundamental re-working of the notion of the "risk-benefit ratio" and propose principles and actions necessary for radical reform of the management of drug-related harms."(1)

1- Amalyste "La gestion du risque médicamenteux grave". www.amalyste.fr accessed 8 February 2012: 7 pages.

Translated from ***Rev Prescrire*** **May 2012; 32 (343): 377**

Medical devices: marketing authorisations are needed

The Mediator° disaster highlighted the weaknesses in health authorities' regulation of the pharmaceutical market. The Poly Implant Prothese (PIP) breast implant scandal shows that the situation is even worse for medical devices.

Inadequate regulation. Under European regulations, supervision of the medical devices market is largely outsourced to various "notified bodies" that are supposed to audit medical device manufacturers, rather than assigning responsibility to health authorities (1,2). There is no need to obtain Marketing Authorisation (MA) or to demonstrate a favourable harm-benefit balance in clinical use: the product has only to meet the technical specifications to obtain CE marking (1).

The European Commission too susceptible to industry influence. In 2008, following a public consultation it organised on the legislation of medical devices, the European Commission reported "*the rejection of a larger role for European Medicines Agency by the vast majority of respondents, (…)* [fearing] *the adoption of a pharmaceuticals-like regulation for medical devices, (…)* [leading] *to undue delays and higher costs for placing new devices on the market, which (…) would have an adverse effect on small- and medium-sized enterprises, which make up around 80% of the sector"* (3).

The Commission did not take into account the fact that most of the "respondents" to the consultation had conflicts of interest, i.e. medical device manufacturers and other interested parties, who were defending their commercial interests. Of the 200 respondents, 92 were from the medical device industry, 18 were notified bodies that grant the CE mark, and 7 were experts and consultants, while only 33 organisations represented healthcare professionals and 8 represented patients (**a**)(3).

Business versus patients' interests. The Commission concluded that if Marketing Authorisation were required for medical devices, it would not improve public health, but would be detrimental to competition and innovation in the industry, *"and thus ultimately be against patients' interests"* (3). The Commission has chosen sides: industry comes first, not patients.

In reaction to the PIP breast implant scandal, the European Commission tried to reassure the public by announcing *"tighter measures aimed at tracing medical devices"* (4). Traceability is certainly necessary in dealing with the harm caused by dangerous devices. But it is far more important to prevent harm, by assessing the harm-benefit balance of medical devices before considering their introduction to the market, beginning with those that pose the greatest risk.

a- *The Medicines in Europe Forum and other representatives of civil society responded to this consultation by calling for tighter regulation of medical devices, and above all for marketing authorisation to be obtained before market launch (ref 5).*

Selected references from Prescrire's literature search.

1- Prescrire Réaction "Distinguer les médicaments des autres produits d'apparence médicamenteuse" *Rev Prescrire* 2011; **31** (334): 572-576.
2- Prescrire Rédaction "Conflits d'intérêts: les dispositifs médicaux aussi" *Rev Prescrire* 2012; **32** (339): 69.
3- European Commission "Recast of the medical devices directives - Summary of responses to the public consultation" 5 December 2008. ec.europa.eu accessed 11 January 2012: 15 pages.
4- "EU evaluates danger, number of faulty breast implants. www.euractiv.fr accessed 11 January 2012: 2 pages.
5- EAHP, HAI Europe, ISDB, Medicines in Europe Forum "Recast of the European Medical Devices Directives: an opportunity to reinforce patient safety: 4 pages. english.prescrire.org/en/79/207/46302/364/355/SubReportDetails.aspx.