Translated from ***Rev Prescrire*** **April 2011; 31 (330): 304-306**

Prescrire's proposals to France's national conference on medicines policy: patients' interests and public health should come first

● **In the wake of France's Mediator° scandal, Prescrire offers 57 proposals on how to get medicines policy back on course.**

Rev Prescrire **2011; 31 (330): 304-306.**

The public health disaster caused in France by Mediator° (*benfluorex*) demonstrated just how inadequate the regulation of the market for medicines is, and how serious the human consequences.

Prescrire has proposed a series of measures to protect the public from any more drugs like Mediator°, and more generally to get medicines policy back on course, with priority given to patients' health needs and to public health.

These recommendations are based on *Prescrire's* experience and analysis over the past 30 years, as expressed in a large number of articles published in our French and English editions.They share many of the recommendations made in the French Senate report written by Ms. Hermange and Ms. Payet (2006) and the National Assembly report by Ms. Lemorton (2008).

Prescrire's proposals have been drawn up in the context of the "Assises du medicament". This national conference on medicines policy has been convened to discuss what changes ought to be made in light of the multiple failures of the system observed in the Mediator° disaster. *Prescrire* has accepted the invitation to participate in this conference.

More stringent criteria for marketing authorisation

1. In marketing authorisation applications filed by pharmaceutical companies, require complete results of clinical trials comparing the new drug against the drug(s) of reference, in their optimal conditions for use.
2. Bring about a change in legislation at the European level requiring that marketing authorisation applications demonstrate the added therapeutic value and packaging safety of new drugs with a high level of evidence, demonstrated in the normal conditions of use.
3. Provide public financing for comparative clinical trials that allow drugs to be objectively rated among therapeutic strategies, in terms of their risks and their benefits.

Public financing for continuing education and information about medicines

4. Provide public financing for activities that currently appear to be financed by pharmaceutical companies, but are financed de facto by the national health insurance system, via its coverage of pharmaceutical expenses in hospitals and in the community: research work in hospitals; training of healthcare professionals in universities, hospitals and in the community; activities of patient groups.

Strong expertise on the part of regulatory agencies and other authorities dealing with medicines

5. Reinforce the number and skills of experts who are independent from pharmaceutical companies, especially by developing clinical research that is publicly funded.
6. In the career of healthcare professionals, particularly those in hospitals and university hospitals, assign greater value and rewards for work done as an outside expert for public agencies than for participation in work financed by pharmaceutical companies.
7. Significantly reinforce agencies' in-house expertise.
8. Encourage the development of independent experts at the international level, especially at the European level.
9. Diversify and cross-compare the viewpoints of the various experts in committees and working groups (epidemiologists, primary healthcare providers, patients).
10. Bring in new heads of working groups and committees, new institutional representatives, on a regular basis so as to increase the number of experienced people and to enhance skills.

Widespread transparency amongst agencies and other authorities dealing with medicines

11. Extend the requirement of transparency to all the work done by regulatory agencies and other competent authorities (including making available the documents used to develop positions or make decisions).
12. Implement a system of independent verification of declarations of interests.
13. Implement a system of sanctions in case of non-disclosure of interests.
14. During meetings of committees or other working groups, hear from the participants who have an interest in the company involved (either directly or as a competitor), e.g. the clinical trial investigators; then require all participants (experts or others) who have an interest (be it major or minor) in any company involved to leave the room, during the discussion leading up to a position being taken or a decision being made.
15. Implement and apply sanctions in case of participation in a position being taken or a decision made, in case of an interest in the company affected by the position or the decision.
16. Increase the transparency of debates, position-taking and decision-making: detailed agendas of meetings announced ahead of time; documents upon which experts have made statements (documents supplied by companies and those obtained elsewhere). All clinical data or other data that are important in making recommendations (presentations, etc.) must be made public.
17. Ensure that experts' minority opinions are expressed, by requiring that the voting results be included in minutes, with the details and the justification of the minority opinions, position by position or decision by decision (video recording or verbatim reporting of the sessions would allow this objective to be met).

18. Make minutes of meetings available online and readily accessible, within 2 weeks after the meeting.
19. Ensure the follow-up (traceability) of recommendations made at each level of regulatory agencies, administrative and ministerial authorities in charge of medicines, with publication, when applicable, of the reasons why recommendations were not taken into account.

Robust, proactive pharmacovigilance

20. Ensure that decisions in pharmacovigilance matters are made independently from marketing authorisation bodies.
21. Facilitate the required reporting of adverse effects by healthcare professionals, by simplifying the procedures (online reporting).
22. In the context of the continuing education of healthcare professionals, assign greater value to reporting and to participation in pharmacovigilance studies or surveys with regional pharmacovigilance centres, than to participation in work carried out by pharmaceutical companies.
23. Encourage patients to report adverse drug effects to regional pharmacovigilance centres.
24. Encourage reporting by healthcare professionals and by patients of the adverse effects of drugs (old or new) that are under particular scrutiny, by means of a symbol printed on the drugs' packaging and information included in the leaflet.
25. Regularly inform healthcare professionals of the follow-up given to their reports by facilitating access to the work of the regional or national pharmacovigilance centres, notably through a newsletter.
26. Encourage the undertaking and the public financing of post-marketing authorisation studies, as decided by the marketing authorisation or pharmacovigilance committees.
27. Apply sanctions, in particular financial penalties, for non-completion within the designated time period of post-marketing authorisation studies that marketing authorisation or pharmacovigilance committees have requested from pharmaceutical companies.
28. Develop the capabilities of health insurance providers and healthcare facilities to analyse prescriptions and to carry out pharmaco-epidemiological studies.
29. Give regional pharmacovigilance centres the staffing and the financing they need to process reports from healthcare professionals and patients, to conduct independent pharmacovigilance studies, and to educate and inform healthcare professionals and the public.
30. Make available online all data recorded in the databases of pharmacovigilance centres (regional, national and international); all data gathered in updates such as Periodic Safety Update Reports (PSURs); all detailed "follow-up measures" required by national and European drug agencies.
31. Publish in a timely manner all pharmacovigilance data likely to encourage healthcare professionals and patients: to report the adverse effects experienced with this or that drug; to take special precautions; or to reconsider current treatments.
32. Make decisions to suspend or to withdraw marketing authorisation without delay, on the basis of an unfavourable risk-benefit balance, particularly when there is an alternative treatment with a better risk-benefit balance; with the benefit of the doubt given to the patient and not to the drug.
33. Require that the withdrawal of a drug from the market be preceded by online publication of the minutes of the pharmacovigilance committee that proposed the withdrawal, as well as the documents underlying that decision.

Initial training of healthcare professionals free from industry influence

34. Make the use of the International nonproprietary name (INN) of drugs mandatory in the initial training of healthcare professionals, together with teaching about the meaning of INNs and their common stems.
35. Significantly develop the teaching of pharmacology, and in particular clinical pharmacology, in the training of physicians, pharmacists and other healthcare professionals.
36. Develop, in the training of physicians, pharmacists and other healthcare professionals, specific teaching on pharmacovigilance: its importance, its concepts, its methods, the classic case studies (*thalidomide*, *diethylstilbestrol* (DES), *rofecoxib*, fenfluramines including *benfluorex*, etc).
37. Develop, in the training of physicians, pharmacists and other healthcare professionals, teaching about patient safety and the management of error involving medications and healthcare products.
38. Develop independence and transparency of interests for instructors.
39. Require universities and university hospital training facilities to establish a publicly accessible file of their staff members' interests in companies doing business in the healthcare arena (healthcare products in general, medical devices and equipment).
40. Make the premises for the training of healthcare professionals independent of healthcare product companies ("advertising-free and gift-free schools and hospitals"), by way of public financing sufficient to cover teaching and research activities; equipment, research material, participation in conferences, exam preparation.

Continuing education of healthcare professionals truly devoted to improving practices

41. Effectively implement mandatory continuing education for healthcare professionals, with public financing.
42. Develop a network of academic detailing independent of pharmaceutical companies, in charge of distributing reliable information to healthcare professionals.
43. Develop multidisciplinary training programmes bringing together physicians, pharmacists, nurses, etc.
44. Reinforce the accreditation process for providers of continuing education: more specific requirements, high norms for the quality of programme content, independence from pharmaceutical companies, regulation, sanctions.
45. Develop tools allowing healthcare professionals to evaluate their practices and to make changes, in the interests of patients.

Quality information for the general public, to foster joint decision-making by patients and healthcare professionals

46. Develop health education in schools covering diseases, prevention, drug or non-drug treatments, in a manner that is independent from industry (drug companies, food companies, etc.).
47. Increase the number of quality public campaigns informing the general public about the rational use of medicines.
48. Implement, with public funding, a complete database of free information about drugs on the market (assessment report, summary of product characteristics, report by the committee that assesses the medical benefits of new drugs and advises on drug reimbursement, a quality bibliography of relevant material, etc.).
49. Get patients and users more involved in the development of information campaigns about medicines.
50. Require that patients' groups and users' groups disclose their sources of financing. ▶▶

► **51.** Encourage membership in patients' groups or users' groups.
52. Finance therapeutic education with public funds.

Professional practices first and foremost in the interest of patients

53. Publish pharmaceutical companies' financing of healthcare professionals online (list of contracts by healthcare professional and by company).
54. Apply the rules of transparency and of management of conflicts of interest that apply to national institutions to the regional and local bodies in charge of medicines: hospital medical committees; purchasing authorities; the French body that oversees medicines, medical devices and therapeutic innovations (*Observatoire des médicaments, des dispositifs médicaux et des innovations thérapeutiques, Omédit*); etc.
55. Ensure that computer programmes to aid in prescription, drug dispensing and pharmacy management are independent from healthcare products companies.
56. Provide compensation for health and counselling services provided by pharmacists in community pharmacies and in hospitals, in order to optimise prescriptions and treatment follow-up: advice, health education, patient assistance and support.
57. Make corresponding changes in the way that pharmacists are remunerated, in order to reconcile the tasks detailed above with the financial viability of community pharmacies.

Translated from ***Rev Prescrire*** **January 2011; 31 (327): 61**

Patient education: keep the best, avoid the rest

● **Beware of commercially biased education.**

Therapeutic education is intended to help patients become more aware of factors affecting their health, as well as their illnesses and treatments. As such, it whets the appetite of advertising agencies and drug companies, particularly those seeking to increase patient loyalty to products used for long-term treatment. For example, this argument was used at a conference devoted to patient compliance: "*Behavioural influences and compliance: learn how empowering patients can improve your return on investment*" (1).

How is this new market controlled? In France, the law "Hospitals, patients, health and territories" (HPST) is intended to create a sound framework for patient education programmes, at least on paper… (**a**)(2-4). But many uncertainties remain, including effective control by regional health agencies (that have many other responsibilities); the role of patient groups, especially in terms of support programmes provided to patients, that must be protected from conflicts of interest when a programme is funded by companies; the quality and independence of educators; and the role of healthcare professionals.

Key role for healthcare professionals. The law gives healthcare professionals a number of important responsibilities, such as asking patients if they want to participate in educational programmes; coordinating programmes and playing a direct educational role; approaching patients on behalf of administrators of educational programmes, etc.

Patients need healthcare professionals to deliver quality care, not to act as salespeople for commercial therapeutic education programmes. All those concerned with quality healthcare must remain vigilant and critically examine available programmes. *Prescrire* encourages healthcare professionals and patients to inform us of any programme that appears suspect or inappropriate.

Once again, the responsibility lies with healthcare professionals firmly committed to acting in the best interests of their patients.

a- The section in this legislation concerning therapeutic education makes a distinction between therapeutic education programmes, training programmes (in the use of a drug or medical device) and patient support programmes (providing advice and assistance to patients). On 10 February 2011, only the texts dealing with patient support programmes had not been published.

1- "7th Annual Patient Adherence & Engagement Summit. 19th-20th October 2010" www.eyeforpharma.com accessed 21 September 2010: 2 pages.
2- "Code de la santé publique. Partie réglementaire. Titre VI: Éducation thérapeutique du patient" www.legifrance.org accessed 20 September 2010: 12 pages.
3- "Arrêté du 2 août 2010 relatif au cahier des charges des programmes d'éducation thérapeutique du patient et à la composition du dossier de demande de leur autorisation" *Journal Officiel* du 4 août 2010. www.legifrance.org accessed 20 September 2010: 5 pages.