The “just say no…” Charter, 2005

Association Mieux Prescrire (AMP) is the owner and administrator of la revue Prescrire and Prescrire International. AMP seeks to defend a number of core values such as independence, ethical care, and placing the patient at the centre of the decision-making process and health care systems.

AMP has around 300 members who are increasingly aware that there are many obstacles to these core values. At its December 2004 General Assembly, it was therefore decided that health professionals must sign on this ‘just say no…’ Charter every year in order to be granted AMP membership. This obviously applies to Prescrire editors.

The signatories of this charter wish to ensure that health professionals’ activities and decisions are dedicated solely to serving patients’ best interests.

We are aware that health care, teaching and research activities can be subject to influences that can undermine health professionals’ independence and ethics, such as:

- economic and financial influence from pharmaceuticals firms through direct and indirect promotional campaigns aimed at patients and health professionals, through the funding of information resources and initial or permanent training initiatives, and pressure on the public authorities;

- economic, political and financial influence from national or supranational bodies responsible for drafting or applying regulations or for managing preventive, diagnostic and treatment resources;

- the personal interests of the professionals themselves; we are aware that patients too can be influenced by direct or indirect approaches, biased information and funding with a hidden agenda;

- funding of patient groups by the pharmaceuticals industry;

- dissemination of unsubstantiated information, or even pure advertising by drugs manufacturers, via the consumer media, opinion formers etc.;

- the organisation of so-called health awareness campaigns by the industry. The signatories pledge to work towards quality care and to:

- refuse any direct participation that goes against this aim, especially drugs manufacturers’ involvement in health issues;

- refuse benefits in kind, gifts and subsidies from pharmaceuticals firms and other bodies likely to be serving their own interests rather than those of the patients, both individually and on behalf of the professional bodies they serve on;

- be wary of pharmaceuticals firms’ promotional activities (advertising, sales reps’ visits, “opinion-formers”, etc.), so as to distinguish, or at least compare them, with independent source of information;

- choose instead independent sources of information and favour comparative information;

- choose, whenever possible, professional, initial and permanent training that is independent from any kind of subsidy from pharmaceuticals firms or other bodies likely to be serving their own interests rather than those of the patients;

- provide patients with information from reliable, quality sources so as to share decision-making with them on the basis of dependable information.

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2004: Lies and damned lies

Prescrire’s Medical Representative Monitoring Network was created 14 years ago and its annual reports have shown a remarkable consistency in the methods employed by medical reps. The tools may change: more reps are now promoting several companies’ products; computers are omnipresent; and there is a greater focus on heavy prescribers (1-3). However, the basic trend is the same: benefits are stressed and risks minimized.

A year of pseudo innovation. In 2003 most rep visits reported by the Network focused on old drugs, isomers, metabolites, combinations, range extensions or me-toos (4). The trend continued in 2004, reflecting the lack of true innovation. Most drugs promoted to Network observers were me-toos belonging to already well-represented drug families. They included, for example, alteplasmin, dustanesteride, manidipine, nebivolol, rosvastatin, valdecoxib (finally not marketed in France after the prelaunch phase (5)), and zofenopril. Other reps promoted copies with fantasy names such as Divarius® (paroxetine), and range extensions such as Vastarel® 35 mg (trimetazidine).

In total, 50% of reported rep visits focused on new products, but the majority of these new drugs offered no advantages over existing products.

Accompanying information: not reliable. A medical reps Charter signed in late 2004 by the French Pricing Committee and representatives of the pharmaceutical industry states that medical reps must provide prescribers with the French pharmacoeconomic Committee’s assessment of the medical benefit of the drugs they promote (6).

Despite this regulatory requirement, the Committee’s assessment was only voluntarily provided to physicians in 5% of reported rep visits in 2004. This was a slight improvement over 2003, but still virtually negligible.

The Charter also states that medical reps must not offer gifts of any sort, even when requested by the prescriber. These include office materials and discounts (travel checks, gift vouchers, etc.) (6).

Draastic changes are needed if drug companies are to respect the Charter: all sorts of gifts were offered to Network observers in 2004, ranging from minor office materials to dinner invitations for the prescriber. These include office materials and discounts (travel checks, gift vouchers, etc.) (6).
Still too many analgesic mixtures

In the early 1980s many preparations sold over the counter in France contained up to eight active substances with various effects, such as nonsteroidal anti-inflammatory drugs, caffeine, opiates, barbiturates and antihistamines.

“Anti-mixture” measures in 1982. Work by the French health authorities led to welcome but partial changes in composition, such as the withdrawal of amiodopyrine (a para-amino analgesic); prescription drug status for noramidopyrine (risk of agranulocytosis) and phenacetin (an antipyretic analgesic carrying a risk of nephropathy, haemolytic anaemia and methemoglobinemia); and a total dose limit of 8 grams for boxes of paracetamol (to reduce the risk of liver damage after overdose) (1-4).

Further improvements in the 1990s. The composition of some analgesic-based preparations has since been further simplified, such as the gradual disappearance of phenacetin (5); barbiturates (6,7); butalbital (8); quinine derivatives (9); and clearance of bromide from one product (10,11,12). Note that at these changes often consisted of replacing one substance with another, considered less harmful (paracetamol replacing phenacetin, for example).

The French medicines agency era: bad analgesic mixtures still on the market. Analytical combinations containing three or even four active substances are still on the French market, usually with authorisations decades old. It is well known that these combinations have a negative risk-benefit balance, notably because of additive adverse effects, drug interactions, and risks associated with concurrent intake of another preparation containing the same substances.

Several obsolete substances are still available, such as belladonna powder combined with codeine, caffeine and paracetamol, and opium powder combined with paracetamol and caffeine. Caffeine is ubiquitous, despite the known risks: thus combinations can lead to inconsistent patient information leaflets. For example, the Preparations section of the Prontaligene leaflet specifies that “this drug may cause encephalitis and must not be taken at the end of day”, while the section on Driving and Machine Use draws attention to the risk of drowsiness.

These mixtures have numerous disadvantages, including a risk of additive adverse effects and interactions; different regulatory statuses; risks of interactions with dietary components (especially alcohol and caffeine); various trade names bearing little relevance to the nature of the components; and uninformative packaging (international non proprietary names mentioned in small print on the side of the box but not on the blisters); and incoherent patient information leaflets.

The French medicines agency seems simply to ignore these facts, doing nothing to withdraw these mixtures from the market.

European measures to be applied in France. European Directive 2004/27/EC stipulates that fixed-dose combinations containing up to three active substances must mention all three international non proprietary names on the outer and inner packaging (14). And, hopefully, the new obligation that information leaflets be tested on panels of potential users will further underline the incoherence of such mixtures.