

Information for consumers

Danielle BARDELAY

European Group of the ISDB
(International Society of Drug Bulletins)

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The recent stir over the possible lifting of the ban of direct-to-consumer advertising of prescription drugs in Europe has tended to overshadow what really matters when it comes to 'information for consumers'.

Information for 'consumers' or for 'citizens'? Citizens in good health or potential patients? What sort of information: on health matters and a healthy lifestyle, on health problems, or just on medicines?

The best way to deal with many health problems is to promote healthier living, even if some patients will need drugs. And lifestyle measures do not only concern cardiovascular diseases, osteoporosis or lung cancer. The fight against diabetes, asthma and AIDS, for example, which are likely to be first targets of DTC promotion authorised in Europe, also involves prevention, screening and lifestyle measures, even if drugs can be especially beneficial in these diseases. Much remains to be done to improve general health information in Europe.

But as the focus of this workshop is medicinal products, the question is "just what type of information does the patient, or the average citizen, really need?"

First and foremost, comparative information to make enlightened choices

A well-informed citizen, a patient and relatives:

- can understand the precise place of drugs in the overall management of a given health problem;
- can participate fully, with the health professionals, in the treatment decision and choice of drug therapy. This choice will depend on the balance between the likely benefits and potential adverse effects of available drugs, and also their cost-effectiveness;
- will understand the optimal conditions in which the chosen drugs are used;
- can contribute to monitoring adverse effects, especially those of prescription-only products, which carry a higher risk than over-the-counter products.

If they are to be empowered in this way, European citizens need a basic understanding of how the body works, and what can go wrong. Getting familiar with concepts such as the risk-benefit ratio, epidemiology, pharmacovigilance, the placebo effect, etc. would also be useful. This knowledge can be acquired within the family, at school, and in society.

When illness strikes, an individual needs comparative information on available therapeutic options: this means not only drugs, but also surgery, physiotherapy, psychotherapy, dietary measures, etc.; sometimes the best option is not to treat. Reliable comparative information can only be obtained from sources that have no direct financial ties with manufacturers of drugs or other devices or methods. Only full independence can guarantee valid comparisons.

When treatment includes drugs, the patient needs specific information on their use. This information can be provided by the dispensing pharmacist or the nurse administering the treatment, or can be obtained from the packaging and patient leaflet.

The patient also needs reliable information throughout the treatment period, especially on potential side effects, the patient needs to know how and when a treatment should be stopped.

A SPECIFIC ROLE FOR EACH ACTOR

Four actors are involved on the field of information on medications. The quality of the information depends on the balance between the role of these four actors.

The first actor is the group of patients. These citizens are often considered as consumers but are not necessarily there to consume. They are in no way passive, as reflected by the multitude of self-help groups, patient organisations and networks that have sprung up worldwide in recent decades, with the aim of representing patients' interests and keeping them informed. As regards DTC promotion, which I shall come to shortly, the recent reports and position statements from Public Citizen in the United States, the British Consumers' Association, Health Action International or the European Bureau of Consumers' Associations are good examples of this vitality (1,2,3,4). Patient organisations also play an important role, although a growing number are directly dependent on drug companies, or are even created by them, and are thus no longer in a position to provide independent drug information.

The second group of actors -- health professionals -- are a natural vector for conveying drug information to patients, provided they are independent and competent. Health professionals, and especially family doctors, specialists in preventive medicine, pharmacists and nurses, who are in closest contact with patients, are best-placed to bridge the gap between specialised technical information and day-to-day practice. After a few decades of over-reliance of some health professionals on information produced by the pharmaceutical industry, the trend is starting to reverse. The vitality of independent drug information networks is growing, with such organisations as the International Society of Drug Bulletins, and, at the national level, the Therapeutic Initiative in Canada, Arznei-Telegramm Netzwerk in Germany, or *la revue Prescrire* in France, etc. (5,6,7,8). This trend is part of the movement towards evidence-based medicine and also reflects patients' and other citizens' desire to be active, well-informed partners in their treatment. It is noteworthy that more than 25% of ISDB member bulletins have started to publish articles not only for health professionals but also directly aimed at patients. For instance the *Drug and Therapeutics Bulletin* and *Treatment Notes* in the UK, NPOJIP ("check your medicines to save your life") in Japan, (9).

The third group of actors involved in drug information is the health authorities. This category is often assumed to include health care insurers (social security and private insurance), even though they render different but complementary services to patients. Their nationwide coverage, together with their presence at the local and regional levels, allows these bodies to support or even initiate the spread of information on health education, screening, prevention, and at-risk behaviours. Provided they have the political will, of course.

This is also a major potential source of information on drugs, covering fields as diverse as the use of vaccines and the prevention of side effects. The health authorities and health insurers in some countries also support and initiate information campaigns and independent information sources created by patients or health professionals. After all, it is in their interests to do everything possible to ensure the rational and coherent functioning of the health care system.

The fourth group is the pharmaceutical industry, which produces and sells drugs. Directly or indirectly, the pharmaceutical industry also conducts or sponsors a large proportion of all research and development of new drug substances. It is unfortunate that European public research organisations have generally failed to adequately deal with unresolved health problems and that a tiny minority of the so-called "new" preparations produced by the pharmaceutical industry really provide an extra benefit for the patient (10,11). But that's another subject.

The pharmaceutical industry has an obligation to provide the information ensuring optimal use of their products. This is the role of the patient information leaflet and packaging information. In principle, this type of information is written with the patient in mind. In contrast, the summary of product characteristics is aimed at the health care professional.

SERIOUS AND REPEATED ABUSES BY THE PHARMACEUTICAL INDUSTRY

In practice, drug companies have failed to fulfil their duty to inform via the patient leaflet and SPC. By completely blurring the dividing line between information and promotion, they have developed highly effective promotional tools and methods that ignore the very special nature and utilisation of the "merchandise" they produce.

Information for health professionals has given way to promotional material overstating benefits and minimising risk through every available medium. The place of the SPC has become highly restricted, and in some cases has simply evaporated, as witnessed by the majority of medical sales visits to practitioners. The spread of exaggerated or deceitful information on the benefits of drugs, and the omission of information on adverse effects, is regularly decried by regulatory agencies and independent monitoring networks such as *MaLAM* in Australia, *Prescrire's* medical rep monitoring network in France, *No Free Lunch* in the United States, or *GRAS* in Belgium, etc (12,13,14,15).

Regarding information for the general public, the pharmaceutical industry has given up trying to create informative package labelling and patient leaflets, concentrating rather on increasingly intensive promotion in the various media. Initially advertising was restricted to self-treatment medications, but this promotional activity is now spreading to an increasing number of prescription-only drugs. This is especially the case in the United States, particularly via companies' websites, which are also accessible in Europe. In addition, drug companies are already using all the other available media, intensively promoting their products, including prescription drugs, either directly or through the use of opinion leaders. The first major campaign of this type to hit Europe was for *sumatriptan* in the early 1990s. Since then, the number of such campaigns has exploded, and now concerns not only products used in obesity or erectile dysfunction, but also in osteoporosis, hypertension or some cancers.

Is the drug industry nevertheless informing patients, or conducting information campaigns on serious health problems? No. The industry's sole preoccupation now, in the current context of cut-throat financial competition and the all-powerful shareholder, is to promote their products in any way possible, including DTCs.

THE DOWNSIDE OF DTC PROMOTION

Some say that DTC promotion would have positive consequences, for example, helping to inform patients who are unaware of they have a medical condition. They say that the poorly informed "consumer", who is desperately seeking information on drugs, would appreciate DTC promotion. Yet the negative consequences of promotional abuses are already visible today.

In the United States, for example, where DTC promotion is widespread and legal, there has been a massive increase in prescriptions (and sales) of prescription-only drugs that have been intensively promoted to the public. Compared to 1998, prescriptions rose by a staggering 34% in 1999 for the first 25 prescription drugs that had been the subject of DTC promotion. This compared with only a 5% rise overall in other prescription drugs. In 1999, drug companies spent 180 million dollars on DTC promotion -- 40% more than in 1998 (16).

DTC promotion campaigns in the US have concerned some medium- and high-risk drugs such as *metformin*, *palivizumab*, *tolterodine*, *trogliatzone*, *bupropion*, or *cypoterone*. Other campaigns have promoted very costly drugs with no proven advantage over cheaper alternatives with better-known adverse effect profiles (3); two examples are *fluticasone* and latest-generation oral contraceptives (3,16,17,18).

A similar situation has developed in New Zealand, where DTC promotion has also been authorised; to such a point that the authorities there are thinking of reversing their decision and again banning DTC promotion (3).

So why should Europe want to create a legal framework for DTC promotion and information campaigns on specific health problems by the drugs industry? Will the European Medicines Evaluation Agency (EMA) be able to keep things under control once this Pandora's box has been opened?

Regulatory measures and good practice guidelines, including those endorsed by the World Health Organisation, have long been unable to prevent abusive drug promotion to health professionals (12,19).

It would hardly be in the interests of public health to risk similar abuses, but this time aimed at patients and the general public. And how can an industry that has just been caught promoting a dangerous lipid-lowering agent be entrusted with providing reliable and unbiased information?

Finally, how can EMA possibly be expected to keep tight control over promotional campaigns when it already has such a close relationship with the pharmaceutical industry? Since the creation of EMA, companies have virtually been free to decide the contents not only of their SPCs but also of the agency's public assessment reports (EPARs), while the public has been hard-pressed to glean the slightest objective information (10,20,21,22,23).

SUPPORT AND DEVELOP INDEPENDENT INFORMATION SOURCES

Optimal drug use can be encouraged in Europe by giving citizens access to information produced independently of the pharmaceutical industry.

Several measures can be taken, for instance:

- health education in schools must be improved, without interference from drug manufacturers (24);
- existing reliable sources of drug information for the public must be listed and promoted;
- complementary independent sources of information aimed at health professionals and patients must be developed, through the media, information centres, websites, networks, etc., based on existing successful models;
- health professionals must be trained to think independently about drugs and be encouraged to inform their patients; this means giving them the necessary time and means;
- health professionals must be trained in communicating effectively with their patients (25);
- health authorities and health insurers must start to engage in high-quality communication on drugs and their correct use, based on experience in certain countries.

IMPROVING THE QUALITY OF PATIENT LEAFLETS

The first thing drug companies should be obliged to do is to produce patient leaflets that are more than incomprehensible legal umbrellas. Research and discussions are required to ensure that drug packaging becomes a true vector of clear, pertinent and practical information.

Regulatory agencies should require that package information is pretested to ensure that it can be understood by patients and promotes good drug use.

This key measure is almost completely neglected at present, despite calls for improvements from consumer organisations and patient associations.

A POLITICAL CHOICE

Enormous efforts are required to clarify the situation surrounding information on medicinal products, so that each European citizen receives reliable comparative information adapted to his or her specific needs. The balance of power between the different protagonists must be corrected. Strong political will is needed to choose between two very different alternatives, namely artificial support for this European industrial sector, whatever the cost, or the development of an effective health care system at the service of the end user, i.e. the patient. Let's hope the authorities make the right choice, because we are all future patients.

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