

RELEVANT HEALTH INFORMATION FOR EMPOWERED CITIZENS

Joint Declaration of HAI Europe, ISDB, AIM, BEUC, Medicines in Europe Forum 3 October 2006

Executive summary

Health information is a fundamental and necessary part of health-care. However, the development of direct to consumer advertising, of disease awareness (or “disease mongering”) campaigns, “compliance programs”, and direct and indirect pharmaceutical industry support of patient’s organizations have blurred the boundaries between drug promotion and health information. If patients are to be able to make informed choices about their health, there needs to be a clear distinction between information and advertising that is disguised as “information”.

Relevant health information should be:

- **reliable:** evidence based (listing data sources), unbiased, and up-to-date, with full transparency on authorship and financing (enabling rejection of information influenced by conflicts of interests);
- **comparative:** presenting benefits and harms of the full range of available treatment options (including, where appropriate, the option not to treat), together with an explanation of the natural history of the disease, or condition; and
- **adapted to users:** understandable, accessible, and culturally sensitive.

Currently, there are many sources of relevant health information for the public both in Europe and internationally. There is room for improvement but to state that a “*patient information depri-*

vation syndrome” exists in Europe is not true. Specific tools have been developed to assess and rate the quality of health information. The aim of these tools is to help both information providers and users to ensure accuracy, quality and relevance to health care choices. This declaration includes many examples of quality assessment tools and information sources provided by health authorities, medical product agencies, health-care assessment agencies, health care providers, health professionals, consumers’ organizations and independent patient groups.

The role of pharmaceutical companies is strictly limited because of their inherent conflicts of interest. Recommendations on treatment choice must be independent both of individual companies that have a product for sale, and the industry as a whole. The statement by industry lobbyists that “*Consumers and patients are effectively excluded from receiving information about their medicine and its comparative effects [because of the] ban [for] drug developers from informing patients [...] even on the developers own web sites*”, makes no sense. Pharmaceutical companies, and all “partners” financed by pharmaceutical companies, cannot provide unbiased comparative information on available drug and non-drug treatment alternatives.

Pharmaceutical companies do have a specific role to play: by law, they must provide well labelled drugs, including patient information leaflets. Directive 2004/27/CE requires package leaflet evaluation by patients. This is an important and much-needed step. Informative packaging and patient information leaflets are likely to contribute to better medication use and prevention of errors.

Proposals for improvement of European citizens access to relevant information include:

- ensuring transparency of medical products agencies to guarantee full public access to pre-market studies of drug safety and effectiveness, and pharmacovigilance data;
- requiring pharmaceutical companies to fulfil their obligations concerning packaging;
- developing and reinforcing sources of comparative, unbiased information on treatment choices;
- optimising communication between patients and health professionals;
- directly including patients in reporting of side effects of drugs;
- putting an end to the confusion of roles between pharmaceutical companies and other actors;
- full implementation and enforcement of the European regulation on drug promotion. ■



ENDORSERS

Health Action International Europe



Health Action International (HAI) is an independent global network of health, consumer and development organizations working to increase access to essential medicines and improve rational use. HAI-Europe is one of the network's four regional coordinating offices (also in Africa, Asia and Latin America). HAI works for greater transparency in pharmaceutical regulation; to promote the rational use of medicines; for better controls on drug promotion and the provision of balanced, independent information for prescribers and consumers. More info: www.haiweb.org

International Society of Drug Bulletins



The International Society of Drug Bulletins (ISDB) is a world wide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently, their members include 57 members in 35 countries around the world. It was founded in 1986. The main requirements for membership are editorial and financial independence, and the quality of the information published. The bulletins audience target are mainly health professionals but also consumers. The overall aim of ISDB is to encourage and assist the development of independent drug bulletins in all countries and to facilitate co-operation amongst them, particularly exchanges of information on new drugs, adverse effects, drug promotion and regulation. More info: www.isdbweb.org

Association Internationale de la Mutualité



The Association Internationale de la Mutualité (AIM) is a grouping of autonomous health insurance and social protection bodies operating according to the principles of solidarity and non-profit-making orientation. Currently, AIM's membership consists of 41 national federations representing 29 countries. In Europe, they provide social coverage against sickness and other risks to

more than 150 million people, either by participating directly in the management of compulsory health insurance or by offering supplementary, alternative or substitute coverage. AIM constitutes a particularly appropriate forum for exchange and debate concerning social protection and health. AIM strives via its network to make an active contribution to the preservation and improvement of access to health care for everyone.

More info: www.aim-mutual.org

Bureau Européen des Unions de Consommateurs



BEUC is a European association, based in Brussels. It was created on 6 March 1962 by the consumer organizations of Belgium, Luxembourg, France, the Netherlands, Italy and Germany, right at the heart of Community policy. BEUC promotes the development of a Single Market that truly works in the interests of consumers. Currently, their members include 40 independent national consumer organisations from some thirty European countries (EU, EEA and applicant countries). BEUC is acknowledged as a trustworthy representative by both decision-makers and opponents alike, thanks in particular to the collective skills, knowledge and expertise of their member organizations. More info: www.beuc.org

Medicines in Europe Forum



The Medicines in Europe Forum, launched in March 2002, covers 12 European member states. It includes more than 70 member organizations representing the four key players on the health field, i.e. patients groups, family and consumer bodies, social security systems, and health professionals. Such a grouping is unique in the history of the EU, and it certainly reflects the important stakes and expectations regarding European medicines policy. Admittedly, medicines are no simple consumer goods, and the Union represents an opportunity for European citizens when it comes to guarantees of efficacy, safety and pricing.

Contents of the full text Declaration

1- IDENTIFYING THE FUNDAMENTAL NEED OF CITIZENS FOR HEALTH INFORMATION

- 1.1. Information as part of health education
- 1.2. Information as part of health care
- 1.3. Information in case of illness
- 1.4. Comparative information for informed decisions

2- TOOLS THAT AID ASSESSMENT AND USE OF RELEVANT HEALTH INFORMATION

3- OBSTACLES TO ACCESSING RELEVANT HEALTH INFORMATION

- 3.1. Quantity outweighs quality
- 3.2. Drug promotion presented as "information"
- 3.3. Lack of time for communication and tradition of secrecy
- 3.4. Diversity of individual needs

4- POSITIVE ACTION IN EUROPE AND ACROSS THE GLOBE

- 4.1. Health authorities
- 4.2. Medical products agencies
- 4.3. Healthcare assessment agencies
- 4.4. Healthcare providers
- 4.5. Healthcare professionals
- 4.6. Consumer organizations
- 4.7. Patients' associations
- 4.8. Pharmaceutical companies obligations

5- PROPOSALS FOR IMPROVEMENT: PUTTING AN END TO CONFUSION OF ROLES

- 5.1. Ensuring transparency of medical products agencies
- 5.2. Making pharmaceutical companies fulfil their obligations concerning packaging
- 5.3. Developing and reinforcing the sources of relevant information
- 5.4. Optimising communication between patients and health professionals
- 5.5. Including patients as actors in the pharmacovigilance system
- 5.6. Considering individual patient needs
- 5.7. Putting an end to confusion of roles
- 5.8. Maintaining and enforcing the European regulations on drug promotion

CONCLUSION

@ Contacts:

Florence Vandeveld fvandeveld@prescrire.org
Rita Kessler rita.kessler@aim-mutual.org
Teresa Alves teresa@haiweb.org

RELEVANT HEALTH INFORMATION FOR EMPOWERED CITIZENS

Joint Declaration of HAI Europe, ISDB, AIM, BEUC, Medicines in Europe Forum 3 October 2006

Full text

PURPOSE AND CONTEXT

Information is an integral part of healthcare: the need for patients to give informed consent is the basis of all care and treatment. Over time, health information has acquired a wider role and greater significance, with an expansion in the range and number of sources of that information. This has raised the question as to reliability of that information.

The recent interest of pharmaceutical companies in the provision of "patient information" in the 80s and 90s has blurred the boundaries between drug promotion and health information. The development by pharmaceutical companies of "direct-to-consumer advertising" (DTCA) in some countries (the USA, New Zealand), of disease awareness campaigns all over the world, and more recently perhaps of disease mongering (the manufacturing of diseases) and "compliance programs", together with direct and indirect industry support of patients organisations have increased the confusion and concerns.

The situation in Europe is now acute. After the rejection by the European Parliament, in 2002, and the European Council, in 2003, of a European Commission proposal to change European advertising regulations to allow pharmaceutical companies to promote "awareness of the availability" of products for asthma, diabetes and AIDS, companies have sought alternate ways of providing "information" to patients and consumers. Although the term 'information' is used, the activities in question include direct and disguised advertising. In essence, the industrial challenge remains the same: lifting the ban on direct-to-consumer advertising in Europe. If patients are to make truly informed choices about their health, clarification is needed to distinguish between information and advertising presented as "information".

1- IDENTIFYING THE FUNDAMENTAL NEED OF CITIZENS FOR HEALTH INFORMATION

Information plays an important role in preventing ill-health, both individually and in a wider society through public health promotion. Potentially, good information has both direct and indirect outcomes. Immediate outcomes include improvements in knowledge and understanding, whereas the longer-term outcomes can be improvements in health and well-being. There are many possible outcomes in between, such as greater confidence to engage in shared decision-making with healthcare professionals. Addressing information needs of patients and consumers is not only a matter of content, but also of communication.

1.1. Information as part of health education

Over-medicalisation of the European population tends to introduce confusion between "health information" and "information on illnesses and medicines". Basic health information includes knowledge on how the human body functions, at different life stages, and on what can help to remain healthy. A solid background on the basic concepts such as benefit/harm balance, symptoms/aetiology, etc. is needed to empower people to take more responsibility for their own health and engage more widely in self-care.

1.2. Information as part of health care

Citizens need various type of information to improve their access to health care: information on prevention (screening, vaccination, contraception, etc.), on illnesses and treatments, specific information when they participate to clinical trials (for a real informed consent). Written information is useful, but face to face exchanges, trustful relationship is essential for adapting the content to each situation.

1.3. Information in case of illness

In the case of health problems which require professional assistance, patients and their families need to be able to express their worries and their feelings, they need to be listened to, and to obtain answers to their questions, for example:

- 1- What is the cause of the problem?
- 2- Will the symptoms spontaneously disappear?
- 3- What would be the purpose of tests and investigations?
- 4- Is there anything I can do myself to improve my condition?
- 5- Are there effective interventions to relieve symptoms, cure the disease, or prevent recurrence?
- 6- What are the different treatment options?
- 7- What are the potential benefits and harms of the treatment?
In the short- and particularly in the long-term?
- 8- How can I reduce the side effects if treatment is worth using?

The information needed has therefore to be developed for different purposes, for example to: understand what's wrong, gain a realistic idea of prognosis, understand the processes and likely outcomes of tests and treatments, identify the most relevant options and services, help to cope, learn about available services and sources of help, etc. Such information should enable people to shared decision-making with health professionals.

1.4. Comparative information for informed decisions

Decision-making requires comparative information including the pros and cons of all options. This kind of information is sometimes scarce or lacking due to inadequate or biased research or to the absence of research. However, all comparative data which exist must be accessible to patients as well as health professionals, and to families or other care givers. It includes information on the natural history of the disease (self limiting or with possible repercussions on an individual's life, either short- or long-term) and on the potential consequences of not treating the disease.

Comparative information also addresses different treatment options: different drug treatments, but also non-drug treatment, life-style changes, social support, surgery, physiotherapy, psychotherapy and all other therapeutic means which have been evaluated for a given condition. For each option patients should be able to clearly identify benefits (degree of clinical effectiveness on important outcomes, convenience, etc.) and harms (potential side effects, disturbances of personal and social life, etc.).

2- TOOLS THAT AID ASSESSMENT AND USE OF RELEVANT HEALTH INFORMATION

Various initiatives have been undertaken to provide lists of quality criteria for patient and consumer health information. The following criteria are common to many of these lists:

Reliable: transparent as to the origin of the information (enabling rejection of information influenced by conflicts of interests), evidence based (stating reliable data sources), unbiased, up-to-date;

Comparative: explaining the natural history of the disease, presenting benefits and harms of interventions, the full range of treatment options (including non treatment), enabling informed choice;

Adapted to users: understandable, easy to use, and accessible, in accordance with the cultural context.

Specific tools for assessing and rating the quality of information materials on treatment choices have been developed, in Europe and the world, to train information users in critical appraisal, or to help them identify reliable sources. Such examples should be widely disseminated and employed.

Examples of tools

- DISCERN questionnaire: www.discern.org.uk
- The UK Centre for Health Information Quality (www.quick.org.uk)
- Which? Lists of useful sources (www.which.co.uk)
- Stiftung Warentest list of information sources (www.stiftung-warentest.de)
- Patient decision aids: <http://www.ohri.ca/DecisionAid/>
- HealthInsite: <http://www.healthinsite.gov.au>
- Women's guide for understanding evidence about health and healthcare: www.cwhn.ca
- James Lind Alliance: www.lindalliance.org
- James Lind Library: <http://www.jameslindlibrary.org>

3- OBSTACLES TO ACCESSING RELEVANT HEALTH INFORMATION

The challenge of health information is two-fold: ensuring that the information provided to people is of good quality and patient-centred, i.e. presenting all the options in a balanced way, and ensuring that it is provided as an integral part of their health-care. Several types of obstacles make this challenge particularly difficult.

3.1. Quantity outweighs quality

Sources of health information are increasing in number, especially with the growth of the internet, but "more" does not necessarily mean "better". The reliability of some of this information is uncertain. Even if not biased due to conflicts of interest, health information can be inaccurate, out of date, inconsistent, incomplete or irrelevant, giving patients unhelpful and conflicting messages. It may not be evidence-based. It may not be produced to meet the needs of patients and be difficult to understand and use. If patients and consumers are not equipped with critical appraisal skills, the reliable information is liable to be diluted by the mass of information.

3.2. Drug promotion presented as "information"

The growing amount of "information" disseminated by drug companies or related bodies, often presented as "disease awareness" together with pharmaceutical solutions, is a major obstacle to the provision of objective health information. Such "information" is presented in attractive format, using current marketing methods, and sometimes disseminated through sponsored patients associations, creating a climate of confidence for those who receive such messages.

Pharmaceutical companies have a dual responsibility: to the patients who take their medicines and to their shareholders. Because of this conflict of interest, pharmaceutical companies' information cannot be impartial and should be treated with caution. In an extremely competitive market, with every attempt being made to maximise sales, the pharmaceutical industry cannot be expected to provide reliable comparisons with other drug treatments, non-drug treatments and the not-to-treat option. Hence DTCA masquerades as "information", but is simply promotion to maximise sales. Regulation of these areas of activity is vague or non-pro-active, and the sanctions imposed are often meaningless.

3.3. Lack of time for communication and tradition of secrecy

Ensuring the quality of information is only part of the challenge. The purpose of conveying information is to ensure it meets a person's needs so they can benefit from it. Communication of information requires time and availability to listen to those who receive the information.

Patients, their carers and families are being encouraged to become more empowered and take more responsibility for their own health. However, health professionals often do not take or do not have the time or resources to meet the needs of 'expert patients'. Professionals often lack easy access to certain information (e.g. data on drug side effects) to inform their patients of the potential harms. Lack of transparency by companies and medical product agencies is, in some situations, an obstacle to the communication of balanced information. The challenge also lies in ensuring that whenever health professionals communicate with and inform patients, they do so in a patient-centred way that is free from bias, undue influence or paternalistic values and attitudes.

3.4. Diversity of individual needs

Information needs are complex and they differ from person to person. They can change throughout the course of life, illness and treatment. Differences in physical and/or mental abilities, language, literacy and resources are not always considered.

These factors influence what type of information patients are looking for and how patients use health information. Addressing children or the elderly, migrant populations, persons with visual or hearing impairment or with learning difficulties is a constant challenge. Local, regional, cultural differences should also be considered when adapting information to patients and consumers needs.

4- POSITIVE ACTION IN EUROPE AND ACROSS THE GLOBE

Despite the obstacles mentioned above, examples of good practice exist among the many stakeholders involved in providing health information in Europe. There is room for improvement, and a need to empower people who are confronted with a growing amount of “information”. But stating that a “Patient Information Deprivation Syndrome” exists in the European Union is simply not true: readily accessible sources, adapted to the different national or regional contexts are available, offering patients relevant information to make informed choices.

Article 152 of the Treaty dictates that the European Commission has a role to play in assuring the public health of its citizens. But all actors involved in the healthcare system of each Member State also play a major role in contributing to patient education and information.

4.1. Health authorities (ministries of health and related institutions)

At the EU Member State level, the national health authorities conduct education and information campaigns, both directly through their central and regional services and websites, and also through other publicly funded institutions. Themes include the major public health questions: nutrition, vaccination, smoking cessation, correct use of drugs such as antibiotics, prevention of misuse of drugs such as hypnotics, epidemic situations, etc. In addition, other government bodies provide specific public information on drugs, for example those that may affect driver vigilance. Other examples from outside Europe confirm the important potential role of health authorities in providing education and information.

Examples of Health authority resources

- Belgian health ministry campaigns on good usage of antibiotics, benzodiazepines, etc. (<http://portal.health.fgov.be>) and (<http://www.bcfi.be>)
 - French Institute for Health Prevention and Education campaigns on hepatitis, cancer prevention, vaccinations, etc. (www.inpes.sante.fr)
 - United Kingdom information on drugs affecting driver's vigilance (www.dft.gov.uk)
- Outside Europe:
- Australian Consumer portal of the National Prescribing Service (www.nps.org.au)
 - Health Canada Drug Safety Advisories: www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/

4.2. Medical products agencies (European and national)

These agencies, which are mainly funded by pharmaceutical companies by way of fees for the authorisation process of new medicines, generally focus on drug authorisation and post-marketing surveillance and rarely produce health information. They provide statutory technical information on drugs (summary of product characteristics and patient information leaflet) and some evaluation reports, which might be useful, when not too deeply influenced by their clients. They rarely provide comparative information which helps patients and health professionals to choose treatments. Some agencies nevertheless produce recommendations for the public.

When medicines agencies follow transparency rules concerning the reasons underlying their decisions (as required by the present European legislative framework, but not yet fully implemented), they also provide original information that, although non comparative, is relevant to the public, notably concerning pharmacovigilance measures.

Examples of Medical products agency resources

- Swedish medicines agency recommendations (<http://www.lakemedelsverket.se>).
 - Finnish medicines agency review on drug information for consumers and patients (<http://www.nam.fi>)
- Outside Europe:
- American Food and Drug Administration drug-safety consumer information portal (www.fda.gov/cder/drug/drugsafety/DrugIndex.htm)

4.3. Healthcare assessment agencies

The Agencies for assessment in healthcare, which are usually publicly funded, are in charge of evaluating new and existing therapies and preventive treatments for the purpose of preparing evidence-based political and financial decisions on reimbursement. The information they generate may be useful for patients, and in some cases is presented in appropriate format for the public.

Examples of Healthcare assessment agency resources

- German Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) offers evidence-based advice on treatments and healthcare in its section called Gesundheitsinformation (<http://www.iqwig.de>).
- National Institute for Health and Clinical Evidence (NICE) provides information for both the public and healthcare professionals (<http://www.nice.org.uk/>).
- Swedish organisation Statens beredning för medicinsk utvärdering (SBU) provide advice on available treatments and preventive measures, both online (<http://www.sbu.se>) and in pharmacies.

4.4. Healthcare providers (payers)

Some healthcare providers disseminate information on the rational use of drugs to their clients in the form of leaflets, training, web-based resources. Some also conduct information and disease management campaigns and collaborate with health authorities and health professionals associations to distribute patient-oriented information. Some payers organizations have long experience in providing information to patients and citizens at national, regional and local level.

Examples of Healthcare providers resources

- British National Health Service distributes information on diseases, their diagnosis and treatments through NHS Direct Online (<http://www.nhsdirect.nhs.uk>).
- French Caisse nationale d'assurance maladie des travailleurs salariés campaign on good use of antibiotic has contributed to start reducing antibiotic consumption in a country where it was extremely high (<http://www.ameli.fr/174/DOC/2641/cp.html>).
- Modellverbund "Unabhängige Patientenberatung Deutschland gGmbH, a recent network of independent patients organisations financed by German statutory sickness funds
- German Arzneimittelkommission der deutschen Ärzteschaft produces brochures containing guidelines on the treatment and prevention of various diseases (<http://www.akdae.de>). They are published by Technikerkrankenkasse and other healthcare authorities.

4.5. Healthcare professionals (doctors, pharmacists and others)

In addition to the information and advice they convey in their everyday practice, some healthcare professionals who are determined to avoid pharmaceutical companies influence produce a variety of independent patient-oriented information in the form of printed and/or electronic bulletins and journals. Others media include leaflets and brochures dealing with particular health issues. Healthcare professionals in some countries have also opened permanent information centres, and some centers even help train patients to select their information sources. Other professionals organize training sessions for schoolchildren on matters like generic drugs, communicable diseases such as influenza, etc. Information campaigns on rational use of drugs are also regularly organised by healthcare professionals.

Examples of Healthcare professionals resources

- German *Gute Pillen Schlechte Pillen* jointly founded by three member journals of the International Society of Drug Bulletins (arznei-telegramm, Pharma-Brief, Der Arzneimittelbrief) (www.gutepillen-schlechtepillen.de).
- British *Treatment Notes* edited by the *Drug and Therapeutics Bulletin* belonging to the International Society of Drug Bulletins (www.dtb.org.uk/idtb/portal/public/intro_tn.html).
- Italian Health and Drug Information Centre of the Mother-Child Health Research Laboratory of Mario Negri Institute (www.marionegri.it).
- German organisation *Arzliches Zentrum für Qualität in der Medizin* (www.patienten-information.de).

- Moldovan organisation Medex (ISDB full member) (website under construction).
- Andalusia campaign on international non proprietary names, supported by the regional authority and the public health school (www.easp.es).

4.6. Consumer organizations (European, national and regional organizations)

Most consumer organizations include sections on health issues in their publications. They produce special issues on health and medicines, or specific publications or websites on health matters offering advice and guidelines. Some organizations are specifically oriented towards rational use of drugs, side effects of drugs (identification and prevention), and patients' experiences, amongst others.

Examples of Consumer organizations resources

- Which? offers advice for patients seeking reliable information (www.which.co.uk).
- Dipex collects patients' personal experiences for improving the quality of care (www.dipex.org).
- Stiftung Warentest, publishes "Handbuch Medikamente", a handbook containing up-to-date comprehensive treatment information for patients (also "Handbuch Selbstmedikation", for self-treatment) (www.stiftung-warentest.de).
- Verbraucherzentralen Bundesverband produces information on diseases and their treatments intended for patients and the general public (www.vzbv.de).
- Kilen works particularly on drug adverse effects (patient reporting and prevention) (www.kilen.org).
- Joint actions are conducted by consumers and other independent partners such as the campaign promoting good drug usage based on the INN system, led by Que Choisir, La revue Prescrire, and Fédération nationale de la mutualité (www.prescrire.org/cahiers/dossierDciAccueil.php).

4.7. Patients' associations

By way of number and proximity to patients and citizens, patients associations generate large amounts of health and disease information. They play an important role in transferring knowledge and life skill experiences, particularly on chronic diseases (how to live with diseases and/or disabilities in the short or long-term, either as individual or in the family). Pharmaceutical companies consider these associations as an excellent means of getting commercial messages across to patients, and of strengthening their political pressure. Nevertheless, independent patients associations, having clear guidelines and mechanisms to avoid conflicts of interests, do produce high quality health information and conduct useful information campaigns.

Examples of Independent patient organizations resources

- DES Action is defending victims of diethylstilbestrol (DES) and has generated a wealth of information on this subject (www.desaction.org)
- German Buko Pharma-Kampagne provides critical information on drugs for patients and the public, and also represents patients on the advisory committee of the self-governing healthcare administration in Germany (www.bukopharma.de).
- Belgian Ligue des Usagers des Services de Santé debates about public health issues in day to day patients reality (i.e. generics or smoking ban in restaurants, etc.) and provides practical information (<http://luss.daaboo.net/>)
- Mind, the British National Association for Mental Health is an example of association with a strict policy of independence and producing information for the public (www.mind.org.uk).
- Insulin Dependent Diabetes Trust does not accept funding from the pharmaceutical industry and provides information for the public (<http://www.iddtinternational.org>)

4.8. Pharmaceutical companies obligations

Their role regarding patient information is strictly limited by way of their natural conflict of interest, which cannot give credibility to their recommendations on treatment choice. Stating that “Consumers and patients are effectively excluded from receiving information about their medicine and its comparative effects [because of the] ban [for] drug developers from informing patients [...] even on the developers own web sites”, as lobbyists of the pharmaceutical industry put it, does not make sense since pharmaceutical companies, and all “partners” financed by pharmaceutical companies, cannot provide the comparative information required.

However, pharmaceutical companies must by law provide well labelled drugs and a patient information leaflet included in the packaging. The leaflet content must be accurate, and readable by patients, and Directive 2004/27/CE requires leaflet evaluation by patients. When companies develop informative packaging and relevant patient information leaflets, this may contribute to the better use of drugs and to the prevention of medication errors. There is indeed room for improvement but some examples show the way.

5. PROPOSALS FOR IMPROVEMENT: PUTTING AN END TO CONFUSION OF ROLES

Improving the relevance of patient information, in Europe and across the globe, is a crucial challenge for public health reasons and also for economic reasons, considering the serious consequences of inappropriate drug consumption. There are a number of actions which could contribute to this improvement.

5.1. Ensuring transparency of medical products agencies

Access to drug evaluation data (existence, protocols and results of clinical trials; reasons for agencies decisions granting or modifying authorisations) and to pharmacovigilance data is not yet guaranteed in the European Union. The new regulatory framework (Directive 2004/27/EC and Regulation EC/726/2004) which requires transparency by medical products agencies has yet to be strictly implemented, giving health professionals, patients and citizens access to essential data.

5.2. Making pharmaceutical companies fulfil their obligations concerning packaging

The new European regulatory framework requires good quality labelling of drugs, including for partially sighted or blind citizens, and consultation on patients’ leaflets with targeted groups of patients to ensure that leaflets are legible, clear and easy to use. Member States had to bring the Directive into force no later than October 2005, but many countries did not meet this deadline. Urgent consideration of these practical aspects is needed.

5.3. Developing and reinforcing the sources of relevant information

Readily accessible sources of good quality health information exist in different regional or national contexts, allowing patients and consumers to make informed choices. They should be supported, and other appropriate sources should be developed with local actors in Member States where they are lacking. When needed, public funding of such sources should be guaranteed mid- and long-term.

5.4. Optimising communication between patients and health professionals

Part of the challenge to engage patient in shared decision-making is to provide sufficient time and resources to meet the growing expectations of patients for information. Communication between patients and healthcare professionals needs to be a two-way dialogue. Simple initiatives such as encouragement to prepare consultations with health professionals by writing down all the questions the patient wishes to raise, can help optimise the use of time and the outcome. The use of international non-proprietary names (INN) instead of multiple trade names can facilitate understanding of drug treatments and improve dialogue.

5.5. Including patients as actors in the pharmacovigilance system

Patient reporting of adverse drug reactions is precious and needed. It contributes to a better knowledge of drugs, but also to adequate feedback information. Various Member States already collect reports directly from patients including Denmark, Italy, the Netherlands (LAREB), and the United Kingdom (MHRA yellow card system). Independent organisations also collect this information, e.g. the DGV in the Netherlands, or Kilen in Sweden. Moreover, education on adverse reactions can contribute to the rational use of drugs.

5.6. Considering individual patient needs

European or even national databases, websites, TV campaigns, etc will not replace face-to-face dialogue between patients and health professionals or independent patients organisations. Proximity and common culture are among the ingredients of effective information. European financial support should be given to initiatives which consider these social and cultural aspects instead of focusing on global initiatives which are not a panacea.

5.7. Putting an end to confusion of roles

The production of good quality information for patients and consumers requires a clear separation of the roles of the different actors: clear labelling and informative patient leaflets by drug companies; comparative information on health, diseases and treatments by health authorities, health professionals, payers, consumers and independent patients' associations. Confusion of roles is detrimental to the quality of health information and eventually to the health of citizens.

5.8. Maintaining and enforcing the European regulations on drug promotion

Lifting the ban on "direct to consumer advertising" in Europe would increase drug consumption but would not improve access to relevant patient information. The present European legisla-

tive framework should remain and be rigorously applied to all kinds of drug promotion, even when they masquerade as "information".

CONCLUSION

The authors of this paper call on European institutions and Member States to support the relevant existing sources of health information for patients. They call on the different stakeholders in European healthcare systems to identify and share best information practices, and develop new ones. They call for campaigning to help patients and citizens avoid confusion between health information and drug promotion by the pharmaceutical industry purporting to be "patient information". ■



Main bibliographic sources

- Coulter A et al. "Sharing decisions with patients: is the information good enough?" *BMJ* 1999; **318**: 318-322 (<http://www.picker-europe.org>).
- Coulter A et al. "Informing patients. An assessment of the quality of patients information material" King's Fund, London 1998: 219 pages.
- Consumer's Association "Patient information. What is the prognosis?" Policy report 2003: 81 pages.
- Mintzes B "Blurring the boundaries. New trends in drug promotion" Health Action International 1998: 64 pages (<http://www.haiweb.org/pubs/blurring/blurring.intro.html>).
- "Does the European Patients' Forum represent patient or industry interests? A case study in the need for mandatory financial disclosure" Health Action International 2005: 7 pages.
- Prescrire Editorial Staff "Problems in the EMEA patient information working group. Too drug oriented, too many conflicts of interest" *Prescrire International* 2004; **13** (73): 195.
- Almasi EA et al. "What are the public effects of direct-to-consumer drug advertising?" *PloS Medicine* 2006; **3** (3): e145.
- Krahmer et al. "Call for Action - Patient Information Network (PIN) - European Parliament" Brussels 21 March 2006: 1 page.
- EFPIA "Definition of DTCI - Direct-to-consumer information" http://www.efpia.org/2_indust/glossary.htm#D
- World Health Organization. "Ethical criteria for medicinal drug promotion" Geneva, 1988:5.
- "If at first you don't succeed, try, try again: new phases in the battle for direct-to-consumer advertising of prescription-only medicines in Europe" HAI Europe.
- Series of articles on disease medicine mongering *PloS Medicine* (April 2006) (freely available at collections.plos.org/pdf/plme-03-04-diseasemongering.pdf)
- "The Influence of the pharmaceutical industry" UK House of Commons <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42ii.pdf> (550 pages).
- "Patient Information Deprivation Syndrome" *SCRIP - World Pharmaceutical News* 2004; 2983).
- "Gut vorbereitet zum Arzt- So wird ihnen besser geholfen" *Gute Pillen Schlechte Pillen* 2005 ; (2) : 1-2.
- National Agency for Medicines - Finland "Drug information for consumers and patients- A review of the research" 2006 (<http://www.nam.fi/english/publications/>).
- PhRMA "PhRMA Guiding Principles - Direct-to-consumer advertisements about prescription medicines" Revised November 2005: 11 pages.
- Consumers International "Branding the cure- A consumer perspective on corporate social responsibility, drug promotion and the pharmaceutical industry in Europe"
- Informazioni sui farmaci: <http://www.informazioneisuifarmaci.it/Database/fcr/sids.nsf/pagine/5204EFD13148DCACC1256D0800374BFC?OpenDocument>
- Melander H et al "Evidence b(i)ased medicine - selective reporting from studies sponsored by pharmaceutical industry: review of studies in new drug applications" *BMJ* 2003, 326: 1171-1173.
- Lexchin J et al "Pharmaceutical industry sponsorship and research outcome and quality: systematic review" *BMJ* 2003, 326: 1167-1170.
- Herxheimer A "Relationships between the pharmaceutical industry and patients' organisations" *BMJ* 2003, 326: 1208-1210.
- Dickinson D and Raynor T "Ask the patients-they may want to know more than you think" *BMJ* 2003; 861.
- Ball DE et al "Advertising and disclosure of funding on patient organisation websites: a cross-sectional survey" *BMC Public Health* 2006, 6: 201.