



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods

Brussels, 19 April 2007

**DRAFT REPORT ON CURRENT PRACTICE WITH REGARD TO PROVISION
OF INFORMATION TO PATIENTS ON MEDICINAL PRODUCTS**

**in accordance with Article 88a of Directive 2001/83/EC, as amended by Directive
2004/27/EC on the Community code relating to medicinal products for human use**

Draft Report on Current Practice with Regard to Provision of Information to Patients on Medicinal Products

1. INTRODUCTION

Article 88a of Directive 2001/83/EC, introduced by Directive 2004/27/EC, calls upon the Commission to present a report to the European Parliament and the Council in 2007 on “current practice with regard to information provision – particularly on the Internet – and its risks and benefits for patients”. Article 88a also provides that “the Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good-quality, objective, reliable and non promotional information on medicinal products and other treatments and shall address the question of the information source's liability”¹.

This report reviews the activities carried out by Member States concerning the provision of information on medicinal products in order to respond to the needs of patients/consumers under the applicable legislative framework. Particularly, the report addresses the use of the Internet on the provision of information and its role in improving access to information.

The report is based on information provided by Member States, as well as information published in various literature sources and contributions from patients’ groups, health professionals’ organisations and other stakeholders. The report takes into account discussions within the Pharmaceutical Forum on Information to Patients. Within this overall framework and based on a thorough analysis the report considers in particular:

- Existing information mechanism and technologies on an EU and Member States level;
- The needs of patients;
- The role of different stakeholders.

The report responds to the call on the Commission to consider a strategy on information to patients with clear recognition of the important developments of society. Patients have become more empowered and proactive users of healthcare, increasingly seeking information about their illnesses and treatment options including medicines from an ever growing and diverse range of sources. Patients and consumers have expectations to have access to information on existing medicines and treatments and to be more actively involved in making decisions regarding their treatments. With the increased use of the

¹ The full wording of the article states: “*Within three years of entry into force of Directive 2004/27/EC, the Commission shall, following consultation with patients’ and consumers’ organizations, Member States and other interested parties, present to the European Parliament and the Council a report on current practice with regard to information provision – particularly on the Internet – and its risks and benefits for patients.*”

Following analysis of the above data, the Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good-quality, objective, reliable and non-promotional information on medicinal products and other treatments and shall address the question of the information source’s liability”.

Internet over recent years, ensuring reliable and good quality information available on websites has become essential.

2. POLITICAL AND LEGAL FRAMEWORK

2.1. Political Framework - the G10 process and the Pharmaceutical Forum

Based on wide support by stakeholders, since 1992 Community legislation clearly differentiates between advertisement and information on medicines. While EU rules banned advertisement on medicines subject to prescription to the public and allowed advertising for other medicines under certain conditions, information provisions did not lead to harmonisation amongst the Member States. Several Commission initiatives and repeated public debates focused on the need to address this lack of a Community framework on information to patients in order to respond better to the needs of patients, in the overall interest of health. However, the legal situation has not changed fundamentally over the last 15 years.

A first major initiative of the European Commission addressing information to patients was the setting up of a High Level Group on Innovation and the Provision of Medicines, called the G10 Medicines, which brought together high level representatives of Member States, industry, mutual health funds and patients. The Group had the double goal of encouraging innovation and competitiveness and of ensuring satisfactory delivery of public health and social imperatives. In its report, presented on 7 May 2002, the Group set out a framework of 14 wide-ranging recommendations, including specific orientations on information to patients.

In its conclusions the G10 invited the European Institutions, in co-operation with stakeholders, to produce a workable distinction between advertising and information that would allow patients actively seeking information to be able to do so, and to develop standards to ensure the quality of such information. It had also called for a private-public partnership (PPP) to look at ways patients can have better access to good quality information on their medicines.

In response to the Report, in July 2003 the Commission issued the Communication “A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient- A call for Action”² in which it outlined practical proposals for the implementation of the G10 recommendations. The Communication divided the recommendations into five broad themes, identifying two key actions of particular relevance specifically related to the direct and tangible benefits to patients, namely the need to strengthen the quality and availability of information to patients, and the need to increase the capacity for their collective influence on decision-making at European level.

Further to the Commission Communication, the Council of the European Union adopted a Resolution on “Pharmaceuticals and public Health challenges-focusing on the patients”³ in which it invited the Commission to explore together with Member States the possibility of setting up a European Information System for patients and health

² COM(2003)383 final, 01.07.2003

³ OJ C 20, 24.01.2004, p. 2

professionals, with the objective to provide information on medicines and related conditions that is of high quality, objective, transparent, comprehensive, reliable and up-to-date. The Resolution underlined that patients must be the focus of pharmaceutical policies, emphasising the importance of ensuring better and more accessible information to patients in order to promote the rational use of medicines.

At the time, the Commission acknowledged the increased demand of patients for better quality and availability of information, in particular via the Internet and it committed to providing a realistic and practical framework for the provision of such information on medicinal products.

In line with its political commitments, the Commission had made a number of proposals in the context of the review of the pharmaceutical legislation launched in 2001, to improve the quality and availability of information to patients, health professionals and the public in general. Some of these proposals are now part of the current legislation, and as such are implementing part of the G10 recommendations in the area of information to patients. These new provisions addressed mainly product related information, by improving its access and readability and transparency measures.

However, more far reaching mechanisms to improve and harmonize the access of patients to information have been rejected in the legislative process with reference to the bureaucratic burden caused by enforcement mechanisms and the lack of a clear distinction between advertisement and information. They are therefore not covered by the new legislation.

The lack of a Community legal framework for information for patients has become even more critical from a health perspective. Health challenges like obesity and the ageing society can be met only in active partnership with informed patients. Consequently, health systems increasingly encourage citizens to take a greater role in their own care, and this requires better access to quality information.

At the same time, there is political consensus about the need to safeguard the primacy of the dialogue between healthcare professionals and patients. Nevertheless, patients are progressively more involved in the decision-making regarding their health, and therefore the traditional model based on the exclusive responsibility of healthcare professionals for providing advice is being gradually replaced by partnership, where patients participate more actively in decision-making about their treatment. This change in paradigm has led patients and consumers to increasingly seek information about medicines in a more proactive way, requiring valid information that enables them to make decisions. From a health point of view the informed patient is clearly an asset, as patients take greater responsibility for their own health through preventive measures but also consult their doctors and pharmacists as necessary. Finally the informed patient's attitude and behaviour can contribute to a more rational use of medicines and reduced expenditure of health care systems.

As there had been no response to this evolution of society and in view of the three most crucial issues outstanding from the G10 Medicines process (Information to Patients, Relative Effectiveness and Pricing/Reimbursement), the European Commission created in June 2005 the Pharmaceutical Forum⁴. Three technical working groups, supported by

⁴ http://ec.europa.eu/enterprise/phabiocom/comp_pf_en.htm

a Steering Committee, have been established for each of these subjects. The working groups report to a high level group with a broad membership made up of health ministers from all Member States, representatives from the European Parliament and from ten stakeholder organisations representing industry and public health interests. The Forum is jointly chaired by Vice President Verheugen, responsible for Enterprise and Industry and Commissioner Kyprianou, responsible for Health.

The objective of the Information to Patients Working Group is to develop proposals for improving the quality and accessibility of information to patients on medicines and health issues. The Working Group has developed two main work streams:

- a fact sheet of information on diseases (using diabetes as an example) and developing quality criteria; and
- ways to improve patient access to good quality health information in healthcare environments (in particular, pharmacies and hospitals) and ways to enhance access more generally.

This work is designed to complement that undertaken in preparation of this report by considering improvements that can be made in the broader context of information on medicines, i.e. information on the diseases they are designed to treat and access to information. However, the working group has also contributed with ideas for greater harmonisation of information activities at European level which have been taken into account in the drafting of this report. The working group will be making proposals, following a public consultation, to the next High Level Pharmaceutical Forum which is due to meet at the end of June 2007.

2.2. Instruments under the current Community pharmaceutical legislation

The Community legal framework for the authorisation and market surveillance of medicinal products for human use is primarily contained in Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency⁵ and in Directive 2001/83/EC on the Community code for medicinal products for human use⁶. This framework contains numerous provisions on advertising, information and transparency. However, this information, which is in most cases product specific, is not always directly intended for patients and is often of a very technical nature.

Directive 2001/83/EC provides for a harmonised framework on advertising of medicines at Community level, the application of which remains a responsibility of Member States. This legislation prohibits the advertising of prescription-only medicines to the general public and allows advertising of medicines not subject to prescription.

⁵ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30/4/2004 p. 1 - 33.

⁶ Directive 2001/83/EC of the Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001.

However, the Directive does not include detailed provisions on information on medicinal products, providing only that certain information supply activities are exempted from the advertising provisions. Therefore, the Directive does not prevent Member States from establishing their own approaches regarding the provision of information on medicinal products as long as the above mentioned rules on advertising are respected. These may differ amongst the Member States.

The main provisions of the pharmaceutical *acquis* which have a direct impact on information provided or made available to patients are summarised below. A more detailed account of all provisions in the legislation relating to advertising, information and, where relevant, transparency, is provided in Annex 1.

2.2.1. *EudraPharm – database on medicines authorised in the EU*

Art. 57(2) of Regulation (EC) No 726/2004 tasks the Agency with the creation, in cooperation with Member States, of a database containing information on all medicines authorised in the EU. The database is being developed in stages in order to progressively include information on all medicines authorised via the different authorisation procedures foreseen in the legislation, as well as in all the EU official languages. The first version of the database currently contains information on products authorised at Community level in accordance with regulation (EC)No 726/2004 (the so called “centralised procedure”) only, and has been launched on 6 December 2006 (<http://eudrapharm.eu>).

The database will include the summaries of product characteristics, package leaflets and the labelling of medicinal products, worded in an appropriate and comprehensible manner for the general public.

This database will be a central tool to make existing product specific information available to specific audiences such as health professionals, patients, regulators, industry, other interested parties and the general public. It should seek synergies with other existing instruments (e.g. a link with the EU Health Portal, referred to below, will be established).

2.2.2. *Package Leaflet*

Medicinal products in the EU have to include a package leaflet containing information intended for and relevant to the patient.

Package leaflets are required to be worded in an understandable way and be subject to consultation with target patients groups to ensure their readability. This requires companies, *inter alia*, to perform readability testing and to consider the font size in printed package leaflets. The European Commission services have prepared guidance concerning consultations with target groups.⁷ The EMEA currently prepares an assessment of this new mechanism on the basis of the 18 months of experience and feedback from users.

7

http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2006/09_2006/readability_consultation_2006_09_25.pdf

Currently the majority of Member States provide access to the package leaflet through the Internet.

2.2.3. Public Assessment Reports

For centrally authorised products the Agency is required to publish a European Public Assessment Report which includes a summary written in a manner that is understandable to the public and which contains in particular a section relating to the conditions of use of the medicinal product. Similarly, the national competent authorities are to make publicly accessible the assessment report for each marketing authorisation granted, together with the reasons for their opinion.

In this way, the scientific assessment of quality, safety and efficacy of medicinal products authorised to be placed on the market in the Community is made publicly available to any interested parties. The number of hits on the relevant internet-page of the EMEA confirms the great public interest in these reports.

2.2.4. Information on medicinal products not subject to prescription

The legislation recognises the particularities of medicinal products not subject to medical prescription (the so called over-the-counter or OTC products) concerning the provision of information and the rules for their advertising. The relevant provisions are characterised by the fact that these products are intended to be used by the patient without the supervision of a physician, although the pharmacist's advice may play a role.

The rules applying to the package leaflet and the labelling are fundamentally identical to those applying to prescription medicines. The legal requirements on clarity and readability of this information are particularly important for these products, since in this case the patient is expected to use the medicine without the supervision of a medical practitioner.

Non prescription medicines may be advertised directly to the general public in all media, as provided for in Art. 88(2) of Directive 2001/83/EC. Restrictions concerning specific indications were removed as part of the revision of the pharmaceutical legislation adopted in 2004.

The possibility to advertise non-prescription medicines provided by Community legislation may be restricted by Member States in accordance with Art. 88(3) of Directive 2001/83/EC, which allows Member States to prohibit the advertising of medicines which are reimbursed.

2.2.5. Transparency measures

The current legislation provides for a number of transparency obligations in relation to the evaluation and supervision of medicinal products. These include, for example, making public information on the withdrawal of marketing authorisation applications, distributing appropriate pharmacovigilance information to the general public, or providing information on clinical trials through the *EudraPharm* database.

3. CURRENT PRACTICES ON THE PROVISION OF INFORMATION

3.1. Practices in the Member States

A survey was conducted by Commission services in 2006 amongst the Member States medicines regulatory agencies and the three other countries of the European Economic Agreement Area (EEA) to gather information about their practices in the provision of information on medicines and their experience with the implementation and application at a national level of the legislation governing information on medicinal products, in particular related to the relevant provisions of Directive 2001/83/EC. This was complemented with information gathered by means of a questionnaire prepared for the Pharmaceutical Forum Information to Patients Working Group.

Contributions have been provided by the Competent Authorities of 23 EU Member States and of the 3 other countries members of the EEA. This information is summarised in the report, complemented by an overview of the situation in the Member States of the European Union and the EEA countries, provided as Annex 2. The situation concerning availability of information on the internet is provided in Annex 3.

Based on the information received, there are a significant number of initiatives of varied nature which intend to provide information on medicines and/or illnesses to healthcare professionals and the public. Accurate information on medicines is available from many sources, for example from physicians, pharmacists, pharmaceutical companies and medicines' regulatory authorities.

Probably the most important difference between Member States is the type of information that can be made or is available to the public on the Internet. Some adopt a stricter approach while others allow more information for the public on the Internet.

Others indicated they are currently developing processes to ensure its availability in the short term.

In accordance with the information received, different practices can be distinguished: In some Member States the provision of information is mainly ensured by public authorities, and includes predominantly product related information they have approved. Amongst these Member States, there are some which go beyond the provision of product related information by covering other types of information, such as guidelines on treatments, or comparative information on the value of medicines

In contrast there are a number of Member States which have in place public private partnerships or similar initiatives to provide information specifically intended to cover wider patient needs, such as treatment options or guides covering specific diseases or therapeutic areas. Some of these practices include the participation of the pharmaceutical industry.

Amongst the Member States, approximately 73% provide access through the internet to all or some of the following approved information: the package leaflet and the summary of product characteristics. This information is normally supplied by the National Competent Authorities. 19 Member States indicated that they publish the summary of product characteristics on their websites; while 15 publish both the summary of product characteristics and the package leaflet.

Concerning Public Assessment Reports they are publicly available for all products having a Community marketing authorisation. For medicines authorised by the National Competent Authorities app. 15% of the Member States are also providing access to these reports. Others indicated they are currently developing processes to ensure availability in the short term.

Databases containing information on different aspects related to medicinal products exist across the Member States. However, the content and access to these databases varies widely; some Member States provide free access to basic information on all authorised medicines (e.g. names, composition, price) in order to provide an overview on all medicines and ensure transparency. In some cases these databases may be used by other organisations for their own purposes, such as health services, insurance boards, patients associations or health professionals' organisations. In the Netherlands, for example, the Pharmacists Association (KNMP) uses the official database to develop a database with information on diseases and medicines, together with other sources.

In Germany, the Institute of Medical Documentation and Information runs a number of databases, covering areas such as health technology assessment, medicines and diseases. There are also information platforms directed to patients and doctors which include information concerning illnesses, diagnostic possibilities, and therapeutic treatments.

In Denmark, Finland, Norway and Sweden, the National Competent Authorities have a special information on medicines section for consumers on their website. This includes mostly safety information, basic information about how to use medicines and information about medicinal products. Portugal and the Czech Republic have also an extensive set of information on medicines directed to the public.

Denmark and Sweden publish information on current treatment guidelines. Portugal also publishes a “Prontuario Terapêutico” with comparative guidance on medicines for health professionals, prepared by an expert group under the responsibility of the Medicines Agency (INFARMED).

Various other mechanisms of providing information for the public, such as magazines and journals, leaflets, campaigns, workshops, symposiums have been identified in the Member States. This includes also dissemination through pharmacies and the media.

The aim is mainly to give basic information about treatments and medication associated with diseases, offering informed choice for patients, as well as to educate and train health care professionals.

There are a wide range of public-private partnerships (PPP) across the EU. In relation to activities performed under these partnerships (some involving pharmaceutical industry) or by private organisations, including patient's associations and the pharmaceutical industry, practical examples are given in Annex 2.

A profound assessment on the perception of the different practices in Member States is not available.

3.2. The use of the Internet and other innovative technologies

The Internet differs from the more traditional forms of communication for a number of reasons. It clearly supersedes country boundaries and the information – subject to rare exceptions – is available everywhere in all countries, which have the necessary

technology infrastructures. This may lead to uncertainties in applicable rules and enforcement possibilities. The Internet, more than other forms of communication, requires active action from users before information is available to them. This can specifically influence the distinction between advertising and information.

The Internet is a widely used tool for consumers to search for information. In the European Union roughly half (49.8%) of the population uses the Internet.⁽¹⁾ The Internet usage penetration in the European Economic Area varies between 27.8%, in Poland, and 78%, in Malta. In the end of 2005, this penetration was lower in Eastern Europe (27.8%-50%) and higher in the Nordic Countries (62,5-72,9%)⁽²⁾.

During 2004, about 45% of people who used the Internet obtained information from public authorities' websites.⁽³⁾ Patients also search information on medicines from the Internet more than before⁽⁴⁾. Internet usage varies according to age, education, gender and socio-economic conditions.

Concerning current uses of Internet and other technological developments to provide information on medicines to healthcare professionals and to patients, it is clear that the majority of Member States Competent Authorities (79%) exploit the Internet as a main tool to supply approved information (like the summary of products characteristics, package leaflets and public assessment reports), as well as other information such as details about treatment and medication associated with diseases, administrative data on all authorized products (list of authorised medicines, marketing authorization holders, etc), monographs, comments on the value of medicinal products comparison to other treatments, or scientific reviews.

Patients are now turning more and more to the Internet as the first port of call for general information on medical conditions and prescribed medication. The Internet is a powerful tool and its main benefits are being widely used, well recognized and quickly accessible.

However, there are also issues that need to be addressed in using the Internet for the provision of information to patients. Internet sites have to be properly managed in order to guarantee the reliability and quality of the information they provide.

Firstly, there are issues related to the quality of information. The amount of information provided to different target groups is increasing every day, raising difficulties in finding valid information on medicines. This underlines the need to validate the information provided to patients against agreed standards to ensure an appropriate level of quality. There are however some Member States that have developed mechanisms such as internal procedures or self-control practices for that purpose. In addition, keeping information on medicines on the Internet updated is a challenge for medicine authorities.

Secondly, the access to information on the Internet raises questions. Although this technology is a powerful and simple tool to facilitate access to information it also poses difficulties for certain parts of the population. For example, for certain groups it can be expensive or difficult to access (e.g. the elderly).

Thirdly, the Internet is not able to respond to the specific needs of certain groups of the population and of citizens with special needs (e.g. the disabled). These groups of citizens will require other means to access and receive information.

Besides the Internet, there are also other technological developments available which can facilitate dissemination and access to information, such as interactive television or mobile communication. For example, in the UK the NHS Direct Interactive, based on

digital satellite television, boasts a wide range of information on conditions, health questions, and a guide to healthy living.

3.3. Activities by the Commission and the EMEA

3.3.1. Information on medicines by Directorate-General Enterprise and Industry and the European Medicines Agency (EMA)

The website of the Pharmaceuticals Unit of Directorate-General Enterprise and Industry (http://ec.europa.eu/enterprise/pharmaceuticals/index_en.htm) provides information on medicinal products particularly through the Community Register of Medicinal Products. It comprises a full list of all products authorised by the Community, which include specific information on orphan medicines and on products subject to Community referral procedures.

The approved information on all the medicinal products authorised by the European Commission is published on the website of the EMA (<http://www.emea.eu.int>). This information includes the administrative data, the terms and conditions of the authorisation, the summary of product characteristics, the patient information leaflet and the labelling, available in all Community languages. A European public assessment report is also provided for each product, containing a summary written in a manner that is understandable to the public.

3.3.2. Activities of the EMA with Patients' Organisations

Regulation (EC) No 726/2004 gives additional responsibility to the EMA to develop contacts with consumers and patients. In this context the EMA has established in liaison with the Committee for Medicinal Products for Human Use (CHMP) the EMA/CHMP Working Group with Patients' Organisations.

As a result of the discussions at the level of this Working Group with Patients' and Consumers' Organisations, and in conjunction with the work carried out at the level of the Pharmaceutical Forum, a document on "Recommendations and Proposals for Action from the EMA/CHMP Working Group with Patients' and Consumers' Organisations" has been prepared⁸.

The document identifies four areas for further improvement and contains a number of recommendations on:

- (1) transparency and dissemination of information,
- (2) product information,
- (3) pharmacovigilance, and
- (4) interaction between the EMA/CHMP and Patients' Organisations;

⁸ <http://emea.europa.eu/htms/human/patientgroup/PatientWG.htm>

3.3.3. Health-EU Portal

In addition to the work of the Pharmaceutical Forum, DG Health and Consumer Protection has also launched a Health-EU Portal⁹ in May 2006. Its objective is to provide a trusted single point of entry for health-related information in all official languages. It is designed to provide clear information on a wide range of health-related topics to citizens, patients, health professionals, regulators and policy makers. The Portal also provides access to approved sites in each Member State. It will provide European citizens, for the first time, with a comprehensive and easy to use tool to access information and provides the means for them to take individual action to improve their health.

4. THE PATIENT NEEDS ON THE PROVISION OF INFORMATION AND ITS BENEFITS AND RISKS

This section provides a brief overview of the evidence on patients' needs in terms of information and on the role of health professionals, as well as on some of the implications of the provision of information to patients.

4.1. The role of patients in the healthcare system and their needs

The provision of information on medicinal products requires taking into consideration the needs of patients in the context of healthcare provision. Most sources available point to the increasingly active role of patients in this regard; patients have a right to be informed and in this context they should be able to access information about their health, medical conditions and the availability of treatments. Patients are no longer simply taking what is prescribed for them, but are increasingly involved as managers of their health.⁽⁵⁾ They become intensely involved with their illness, show great interest in health issues and have a constantly growing need for information.⁽⁵⁾

Studies show that consumers are most keen on looking for information about adverse effects of medicines, the level of efficacy of certain products for certain diseases, the costs of treatments and the reasons for the prescription of a specified medicine.⁽³⁾

The available literature also suggests that the diversity of patients' needs cannot be underestimated.⁽⁶⁾ The importance and relative priority of needs vary substantially between different types of patients.² The information available should be relevant to the specific needs of the single individual, which can vary from promotion and disease prevention to understanding and participating in the choice of medical treatments available. This is particularly relevant for patients suffering from chronic or rare diseases.

It also appears that, unlike many other needs, the need for information is very open and dynamic. Personal goals change often through the course of illness and treatment, so new needs and demand for information continually emerge in accordance with specific situations.⁽⁶⁾

Information needs to be understandable and accessible to all citizens, and to take into account such factors as literacy, language, age, mental and physical disabilities,

⁹ http://ec.europa.eu/health-eu/index_en.htm

education, socio-economic situation, cultural differences and access to information technologies. It also needs to be accurate, substantiated by evidence, up-to-date and objective. The sources and the date of the information also need to be specified.

Patients indicate a preference for structured and concise information, clear headings, important sections highlighted, short blocks of text and a good index. No clear preferences are identified for video, audio, computer based, or printed materials ^(7, 12).

4.2. Patient organisations and partnerships

Patient organisations strongly advocate that citizens have the right to high-quality, reliable and validated information about diseases, prevention, treatments and medicines available in order to be more actively involved in decisions about their health. Information is essential to educate and empower citizens and patients, allowing them to make better lifestyle and healthcare choices. Therefore, the focus should be on the availability and quality of information and not its source.

There is also widespread recognition of the Internet as a valuable tool, but there should be criteria developed to ensure that patients can have access to high-quality and objective information on the Internet.

Many patient organisations also acknowledge the role of the pharmaceutical industry as a legitimate source of information on its products, and the importance for the pharmaceutical industry to also provide good quality information through ‘pull’ mechanisms whereby the patient is actively seeking out information and needs to know where and how to access it. However, there is little support for information provision without a demand by patients (‘push’ mechanisms).

4.3. The role of health professionals

Health professionals are and should remain the primary source of health information, particularly on treatments and medicines. A proactive dialogue between physician and patient is essential. However, access to healthcare professionals is unequal in the context of different healthcare systems.⁽⁸⁾

Other health professionals than physicians have a variety of roles to play. Pharmacists have a key role in advising consumers about non-prescription medicines, generally, and about the availability and proper use of prescription medicines. Nurses can also play an important role, particularly in advising hospitalised patients about the proper use of their prescribed therapies.⁽⁸⁾ Best practices on information provision in Community pharmacies and hospitals are also being collated by the Information to Patients Working Group of the Pharmaceutical Forum.

Physicians, pharmacists, nurses and other healthcare professionals may need to be trained to act as information intermediaries (“infomediaries”) to be able to direct consumers and patients to good sources of information.⁽⁸⁾

To maintain a genuine partnership between patients and health professionals in relation to medicines requires a major, sustained effort at communicating with the public. The public needs to be invited and supported to find out more about their own medicines and encouraged to express their beliefs, attitudes and preferences about medicines to health

professionals.¹ The development of this partnership between health professionals and patients in relation to medicines decisions requires access to high quality information.

The link between information to patients and the role of health professionals is underlined by a study carried out by the Dutch Council for Public Health and Healthcare. This concluded that one third of the Internet users search for information on health and/or healthcare several times per year. The percentage has doubled from 2003 to 2004. More and more of these people will enter into a discussion with their physician based on this information: about 25% discuss the information with their physician. Around 25% of those who have visited a physician will look for information on the Internet with regard to what was discussed with them.⁽¹⁰⁾

4.4. The role of the pharmaceutical industry

Pharmaceutical companies possess key information about their products which only in part (through leaflets and labels) is made available to patients.

Consequently, the pharmaceutical industry has the potential to be an important source of information to respond to the growing demand for more and better information by patients and to help reduce the current information gap, provided that there will be adequate rules to ensure reliability, objectivity and quality of information.

Like many patient organisations most, pharmaceutical companies argue that information should be of high quality and not be judged by its source. These companies want to be able to produce non-promotional information for patients about their own medicines and diseases and make it public.

More specifically, the European Federation of Pharmaceutical Industries Associations supports the idea of enhancing the opportunities for internet access to medicine information.

The key interest for the industry is that they should have the same right to provide quality information on their own products. That can be provided alongside that produced by non-industry bodies.

4.5. The benefits and risks of current practices

The risk and benefits of current practices are twofold: On the one hand, EU-legislation provides for a number of information mechanisms as described in Chapter 2 which have clear benefits in informing the public and health professionals in an objective way about individual medicinal products. On the other hand, in view of the absence of clear Community provisions, Member States have established their own approaches on additional factual information to patients, and these approaches differ widely. This situation has created obstacles and risks from a Community perspective:

Firstly, EU citizens have unequal access to information. Access depends mainly on the Member State in question, but also other factors like technological skills, language, income and age whether information is de-facto accessible. In essence, lack of Community legislation currently hampers equal access.

Secondly, the lack of EU quality standards for information to patients increases the risk of wrong, misleading or confusing information creating health risks. One example is counterfeits of medicines illegally advertised and sold while there is no EU-wide framework for the industry to provide information on the medicines and risks of such

counterfeits. Another example are easily accessible internet pages with promotional character for medicines authorised in third countries, while factual information on medicines with the same active substance may not be given on an EU wide basis. This lack of a consistent approach compounds inequalities in access to information between citizens in different Member States.

Thirdly, lack of information may result in uninformed choices. Best practices in Member States demonstrate that information platforms on the internet and in paper format integrate and link specific medicines information with related areas, like information on diseases, diagnostic possibilities and different treatment choices. Such practices aim at educating patients, enabling them to make an informed choice, and training health professionals. Not using existing possibilities throughout the EU means perpetuating existing practices of uninformed choices including late diagnosis, or lifestyle based on low risk awareness.

Although there is insufficient evidence published, an increase in the quality and appropriateness of information available to patients would be expected to contribute to achieve better health conditions and also to contribute to a more efficient use of resources. Better-informed patients are expected to adhere better to treatments and to better understand clinical decisions. This should lead in the long term to social and economic benefits.

The risks that better informed patients will demand more healthcare could raise concerns, especially in respect to an increase in healthcare costs. Although there is some evidence that provision of information may increase referrals to healthcare professionals and possibly costs, there is also evidence of benefits in facilitating earlier diagnosis and management of diseases.

The balance between the benefits and risks of providing information indicates the need for clear rules that apply to information, ensuring its objectivity and avoiding any promotional character. This would also require that benefits and risks inherent to the use of any medicinal product are clearly stated.

5. CONCLUSIONS

Based on a common basic principle that advertising to the public is prohibited for prescription-only medicines, evidence shows that the rules and practices on what information can be available still vary significantly among Member States. Certain Member States apply very restrictive rules, while others allow for several types of non-promotional information to be made available. Some Member States foresee a quite extensive role of public authorities, namely medicines regulatory agencies, in the provision of various kinds of information, while other Member states allow information activities performed under partnerships of public and private organisations, including health professionals' associations, patients' organisations and the pharmaceutical industry. This results in unequal access of patients, and the public at large, to information on medicinal products.⁽¹⁰⁾

At the same time patients have become more empowered and proactive regarding the treatment of their illnesses. Information needs of patients as regards medicinal products range from information on adverse effects to information about efficacy of the medicine to treat the disease concerned, including also information about the costs and duration of treatments.

In general, the internet plays a central role for those who are seeking information, since the information they can find is either mainly provided through the internet or it complements or strengthens other more traditional forms of communicating. Nevertheless, the continued importance of non-electronic tools should be recognised as they are still relevant for large parts of the population (like the elderly, or patients with special needs).

The quality of information is currently very variable, in particular in view of the Internet where the providers have no or limited accountability toward EU citizens. Patients may also still have difficulties in finding valid information on medicines authorised in the EU by national authorities. Mechanisms such as educating consumers, encouraging self-regulation of healthcare providers, evaluation of information by third parties and the use of different enforcement procedures can be potential tools for quality management of information.

Currently public authorities play a central role in providing information, either information they approve as a result of the evaluation of medicines or other types of information prepared for specific purposes, e.g. by expert groups. However, the information that they provide varies widely, thus creating inequalities in access to information about medicines throughout the EU.

Member States authorities may not be in a position to fully address patients' needs in terms of the substance of information and the access via different means. In turn, the pharmaceutical industry possesses the key information on their medicines but this information can currently not be made available to patients and healthcare professionals throughout the EU.

On the legal framework

The rules on advertising of medicinal products for human use are contained in Titles VIII and VIIIa of Directive 2001/83/EC (codifying provisions of Directive 92/28/EC), as last amended by Directive 2004/27/EC. In turn, rules on information and transparency are contained in this directive, as well as in Regulation (EC) No 726/2004 and in other pieces of the Community pharmaceutical *acquis*.

The provisions of Directive 2001/83/EC address specifically the definition and rules on advertising, prohibiting in particular the advertising to the general public of products that are available on prescription only (Art. 88(1)(a)).

The Directive provides also that certain activities are exempted from these provisions, in particular where a marketing authorization holder answers a specific question about a particular product (Art. 86(2) second indent), where he makes factual, informative announcements (Art. 86(2) third indent) or where general information relating to human health or diseases without reference to a particular product is given (Art. 86(2) fourth indent).

Other articles deal with the provision of information, e.g. Art. 88(4) on vaccination campaigns, Art. 89 (1) (b) on minimum information to be provided with all advertising to the general public, and Art. 91 (1) on essential information as part of advertising to healthcare professionals.

The revised pharmaceutical legislation (Regulation (EC) No 726/2004 and Directive 2004/27/EC, amending Directive 2001/83/EC) did not change the rules applying to advertising, although it has introduced additional tools on the provision of better quality information to patients and the public in general, e.g. improved readability of the labeling and the package leaflet, publication of information on the outcome of the assessment process for medicines and reinforced mechanisms to provide information on pharmacovigilance. A number of transparency measures were introduced which will impact positively in the provision of information on medicines.

Regulation (EC) No 726/2004 contains provisions on the publication of a European Public Assessment Report, with a summary written in a manner that is understandable to the public (Art. 13), the public availability of opinions of the Committee for Medicinal Products for Human Use when concerning necessary measures on suspected adverse reactions (Art. 22) and public access to information alerts relating to faulty manufacture, serious adverse reactions and other pharmacovigilance data (Art. 26(3)). Art. 57, establishing the tasks for the European Medicines Agency (the Agency), requires the Agency to disseminate information on adverse reactions to medicinal products authorised in the Community by means of a database appropriately accessible to healthcare professionals and the public, to distribute appropriate pharmacovigilance information to the general public, to create a database on medicinal products including the summary of product characteristics, the package leaflet and the labelling, as well as where appropriate references to data on clinical trials, and to assist the Community and Member States in the provision of information to health-care professionals and the general public about medicinal products evaluated by the Agency.

Directive 2001/83/EC, as amended, comprises equally provisions relevant to information to patients. Art. 21 states that competent authorities shall make publicly available the summary of the product characteristics, together with the assessment report, for each authorised medicinal product; Arts. 59(3), 61(1) and 63 (2) applying to the package leaflet, require a consultation with target patient groups to be carried out to demonstrate the readability, understanding and usefulness of the package leaflet to patients. Furthermore, Arts. 28(2) and 28(3) have introduced the obligation for Member States to harmonise package leaflets for products authorised through mutual recognition or decentralised procedures.

Similarly to Regulation (EC) No 726/2004, Title IX of Directive 2001/83/EC, as amended, devoted to pharmacovigilance, requires public accessibility on information related to adverse reactions to medicinal products under normal conditions of use included in the pharmacovigilance systems operated by Member States (Arts. 102 (2)). The directive also provides for the publication of an annual list of the medicinal products which are prohibited in the Community (Art. 123(4)) and for the setting up of a publicly accessible register of medicinal products subject to an exceptional authorisation to be placed on the market in the absence of a marketing authorisation under Art. 126a.

Directive 2001/20/EC on the conduct of clinical trials has also provisions to ensure patient access to information on clinical trials. Regulation No (EC) 1901/2006 on Paediatric Medicines contains various provisions concerning information on clinical trials and authorised medicines for children.

Information on Current Practices¹⁰

Concerning the different practices in Member States additional information as well as examples on best practices is provided in this annex.

The following table indicates examples of Member States in accordance with the different practices which were identified (cf. 3.1.):

	Provision of product related information	Provision of additional information (e.g. guidelines, treatment options)	Public private partnerships and other initiatives
Member States	All Member States	BE, DK, DE, NL, PT, SI, UK	AT, BE, FR, NL, SE, UK

Some Member States' have provided more detailed information on their current practices. Some of these examples are summarised as illustration.

In the United Kingdom, the Medicines Information Project (<http://www.medicines.org.uk/>) programme brings together a number of stakeholders including the Department of Health, NHS Direct, MHRA, industry and patient and health professional organisations to provide information on treatment options on NHS Direct Online linked to independently authored, non-promotional Medicine Guides for individual generic and branded products. By 2007 this will cover Prescription Only Medicines for all therapeutic areas. Separate strands of work are looking at information about OTC medicines and children's medicines.

Under the Medicines Information Project has shown that the pharmaceutical industry can develop information for patients and the general public about medicines, under the direction of a multisector board that includes patients' organisations, health professionals, and the medicines regulator. This information covering all medicines prescribed in the United Kingdom is being produced in a form called Medicine Guides, starting with treatments for asthma and chronic obstructive airways disease.⁽¹¹⁾

In Austria, the project "Pharmaceutical and Reason" managed and funded jointly by representatives of the Austrian Chambers of Physicians, and of Pharmacists, the Austrian Pharmaceutical Industry and the Austrian Social Insurance Institutions is being developed to secure the provision of high-quality pharmaceuticals. Based on transparency and quality guidelines including a focus on Evidence Based Medicine (EBM), the project releases detailed information and Disease Management Plans (DMPs)/guidelines for health professionals as well as special brochures for patient

¹⁰ This information reflects the contributions received at the date of preparation of this document, which may contain different levels of detail concerning the different Member States. It will be updated in accordance with the information that will be received during the consultation process.

information, with a special emphasis on quality assurance, comprehensibility and consistency with the information for health professionals. These brochures are available for downloading on the Internet, printed copies can be ordered for free.

In Sweden, Fass.se is an internet portal providing information on medicines, developed by the Swedish Association of the Pharmaceutical Industry (LIF), accessible to anyone – patients, healthcare professionals, authorities, available since 2001. Already since 1983 patients had access to a printed directory Fass-Patients. The database is updated by the pharmaceutical industry and it provides only information approved by the authorities, thus no promotional texts or advertising. Pharmaceutical companies can publish their own information available in Fass.se on their websites.

In Belgium information on health and diseases is provided to patients by the Authorities or organisations independent of the industry, whose composition guarantees competence and independence. There is a non-profit-making association named “Centre Belge d’Information Pharmacothéutique”, approved by the federal Minister for public health, which distributes independent information on medicinal products healthcare professionals. This association receives Authorities’ funding; however it has an editorial freedom. To be approved, the association can only be financed by the authorities. Members of this association cannot have direct or indirect interests in a pharmaceutical company.

In the Netherlands, the Ministry of Health supports the websites www.kiesbeter.nl with all kind of patient information, including proper use, prices and reimbursement of medicinal products.

In Finland, the national current care guidelines (<http://www.kaypahoito.fi/>) and information that is produced by patient organisations (e.g. <http://www.diabetes.fi>) include information both on medicines and treatments with versions that are intended to patients.

Besides partnerships and availability of databases in order to provide information to healthcare professionals and consumers/patients Member States’ Competent Authorities had also described others on-going initiatives, no less important, that have been carried by independent organisations, pharmaceutical companies, Health Authorities and so on.

In Finland, the Pharma Industry is producing and publishing as a book a layman version of the medicine compendium (Lääkeopas), which includes Package Information Leaflets. However, the text is rewritten by pharmaceutical companies, so it is not completely the same text that has been approved by authorities. In addition it is not approved by the medicines’ regulatory authorities.

In the Czech Republic regular surveys about pharmacovigilance issues or about defects of medicinal products which can have serious impact on public health are organized in public and press reactions are monitored by the State Institute for Drug Control (SUKL). In addition SUKL answers questions about mission and activities via the information centre of SUKL to the enquirer by phone, email, fax or letter.

In France the Medicines Regulatory Agency (AFSSAPS) has signed an agreement with the Pharmaceutical Industry Union (LEEM) concerning the information available on the websites of the companies. The industry has the ability to set online the full text of the summary of product characteristics, the package leaflet and the public assessment report without additions or changes, in the same part of the website.

Table 1. Information available on the Internet¹¹

COUNTRIES					
	Package Leaflet	Summary of Products Characteristics			Public Assessment Report (PAR)
		Free access	Healthcare professionals only		
AUSTRIA	NO	NO	NO		
BELGIUM	YES	YES	YES		YES
CYPRUS	NO	NO	NO		NO
CZECH REPUBLIC	YES	YES	YES		
DENMARK					
ESTONIA	YES	YES	YES		
FINLAND	YES	YES	YES		NO (under develop.)
FRANCE	YES	YES	YES		YES
GERMANY	NO	NO	NO		NO
GREECE	YES	No	No		
HUNGARY	YES	YES	YES		NO (under develop.)
IRELAND	NO unless provided by companies	No	YES		NO (under develop.)
ITALY					
LATVIA	YES	NO	YES		
LITHUANIA					
LUXEMBOURG					
MALTA	YES	YES	YES		
POLAND		YES	YES		

¹¹ This information reflects the contributions received at the date of preparation of this document, which may contain different levels of detail concerning the different Member States. It will be updated in accordance with the information that will be received during the consultation process.

PORTUGAL	YES	YES	YES		
SLOVAKIA	YES	YES	YES		NO
SLOVENIA					
SPAIN	YES		YES		
SWEDEN	YES	YES	YES		
THE NETHERLANDS	YES	YES	YES		YES
UK	YES	YES	YES		YES
ICELAND	YES	YES	YES		
LIECHTENSTEIN			YES		NO
NORWAY	NO	YES	YES		NO

Table 2- **Sources of information available on the INTERNET (Health authorities, Patients' organisations, pharmaceutical industry, public and/or private partnership).**¹²

Country	<u>INFORMATION AVAILABLE ON THE INTERNET</u>				
	Package Leaflet	Summary of Products Characteristics	Public Assessment Report	Treatment and medication associated with diseases	Others
Cyprus	No	No	No	No	
Finland	National Agency for Medicines www.nam.fi	National Agency for Medicines www.nam.fi	under development	National Agency for Medicines www.nam.fi	-
France	Afssaps' website + websites of pharmaceuticals companies	Afssaps' website + websites of pharmaceuticals companies	Afssaps' website + websites of pharmaceuticals companies	Afssaps, Ministry of Health, Higher Health Authority, National Institute for Prevention and Health Education	if no specific mention of medicinal products websites of: pharmaceutical companies, medical associations, patients' organisations, ...
Hungary	will be available on the website of National Institute of Pharmacy (NIP), www.ogyi.hu from 2007 Now available on the website of the Ministry of Health www.drinfo.hu	available on the website of National Institute of Pharmacy (NIP), www.ogyi.hu	will be available on the website of NIP, www.ogyi.hu from 2007		

¹² This information reflects the contributions received at the date of preparation of this document, which may contain different levels of detail concerning the different Member States. It will be updated in accordance with the information that will be received during the consultation process.

Italy					
Malta	Medicines Authority	Medicines Authority www.medicinesauthority.gov.mt	Medicines Authority	Medicine Policy and Audit Unit cover only Government Formulary List www.sahha.gov.mt/entities/nmpau.html	
Portugal	INFARMED www.infarmed.pt (InfoMED)	INFARMED - www.infarmed.pt (InfoMED)		Portuguese Diabetes Association website at http://www.apdp.pt/	pharmacovigilance issues and information on defects of medicinal products (available at www.infarmed.pt » Alertas)
SPAIN		Health authority: Spanish Agency of Medicines and Medical Devices Address: Parque Empresarial Las Mercedes(Edificio 8) C/ Campezo, 1 28022 - Madrid (Spain) Web: www.agemed.es			Health authority: Spanish Agency of Medicines and Medical Devices Address: Parque Empresarial Las Mercedes(Edificio 8) C/ Campezo, 1 28022 - Madrid (Spain) Web: www.agemed.es
Slovakia	SIDC www.sukl.sk SIDC - State Institute for Drug Control	SIDC www.sukl.sk		Patients' organisations, pharmaceutical industry	
Iceland	IMCA, www.lyfjastofnun.is	IMCA, www.lyfjastofnun.is		Directorate for public Health www.landlaeknir.is, patient organisation, Industry , pharmacychains	www.doc.is
UK	Competent Authority (www.mhra.gov.uk), Electronic Medicines Compendium (pharmaceutical industry); Individual MAH websites.	Competent Authority website (www.mhra.gov.uk); Electronic Medicines Compendium (pharmaceutical industry); individual MAH websites	Competent authority (www.mhra.gsi.gov.uk)	NHS Direct Online, Electronic Medicines Compendium (pharmaceutical industry), Individual MAH websites, Patient Support Groups (various)	
Liechtenstein		delegated to a company (www.documed.ch)	Not published		

Ireland	N/A unless provided by the companies	Provided by the IMB	Will be provided by the IMB, not yet available	Many websites from multiple sources dealing with diseases and medication, not necessarily Irish sites but accessible from Ireland.	
norway					

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