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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

concerning the

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 us

{SEC(2007)1740}

BACKGROUND

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 basic content of the report is based on information provided by Member States, as well as information published in various literature sources and contributions from patient groups, health professional organisations and other stakeholders. The report also 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 mechanisms and technologies on an EU and Member States level;
- The needs of patients;
- The role of different stakeholders.

The draft report was published for consultation on the website of the Pharmaceuticals Unit, DG Enterprise and Industry, on 19 April 2007. Citizens, stakeholders and all interested parties were invited to express their views on the issues presented in the draft report by 30 June 2007. During the consultation DG ENTR received 73 contributions which can be grouped as follows: patient organisations (14), consumer and citizen organisations (4), pharmaceutical industry organisations and companies (18), healthcare professional organisations (16), regulators (9), individual citizens (3), EU and national social insurance organisations (2), media and others (7). All the responses were carefully analysed and taken into consideration whenever possible.

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

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[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".

decisions regarding their treatments. With the increased use of the Internet over recent years, ensuring reliable and good quality information available on websites has become essential.

The report is supported by a Commission Staff Working Document (SEC(2007) 1740) which provides background information on the different parts of the report as indicated in the text.

1. POLITICAL AND LEGAL FRAMEWORK

1.1. 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 detailed overview of this evolution is contained in Annex I of the Commission Staff Working Document.

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 Forum [2]. Three technical working groups, supported by 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. During the two first years of the Pharmaceutical Forum, the Working Group has reached a common understanding on the needs and the challenges existing in the field of information to patients for disease and treatments. A detailed description of the achievements of the Working Group on Information to Patients is included in Annex I of the Commission Staff Working Document.

1.2. 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 Agency[3] and in Directive 2001/83/EC on the Community code for medicinal products for human use.[4].A detailed

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

3 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.

4 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.

description of the current legal instruments is provided for in Annex I of the Commission Staff Working Document.

2. CURRENT PRACTICES ON THE PROVISION OF INFORMATION

2.1. 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 and about the situation concerning availability of information on the internet, provided as Annex II of the Commission Staff Working Document.

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, medicines' regulatory authorities, health professional and scientific organisations and patient and consumer groups. Patients can also use libraries, drug bulletins and other information services to access information.

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.

In 2006-2007 amongst the Member States, approximately 78% 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 National

Competent Authorities (NCAs). 18 NCAs indicated that they publish the summary of product characteristics on their websites; while 16 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. 18% of the Member States are also providing access to these reports. Some 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 2007, there were also other prominent examples of Member States' actions to improve access of patients to information.

In Germany, there are a number of different information platforms which are directed to consumers, patients and health professionals and which provide information concerning medicines, illnesses, diagnostic possibilities and therapeutic treatments. The providers are authorities, healthcare assessment agencies, healthcare providers and professionals, patients' associations and others.

In Denmark, Finland, Norway and Sweden, the National Competent Authorities have a special information on medicines section for consumers on their website[(1)] [5]. This includes mostly safety information, basic information about how to use medicines and information about medicinal products [(1)]. [5] 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 "Prontuário 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.

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[5] Cf. Annex V of Commission Staff Working Document SEC(2007) 1740.

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 II of the Commission Staff Working Document.

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

2.2. 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.[(2) 5] In the European Union more than half (51.8 %, June 2007) of the population uses the Internet.[(3) 5] The Internet usage penetration in the European Economic Area varies between 23.4 %, in Romania , and 75.6 %, in Sweden (June 2007). In 2006, the level of Internet access in households in the European Union (27 countries) was 49 %.[(4) 5] The use of the Internet is increasing. Between 2000 and 2007 (June) the use of the Internet in the EU increased by 206 %. [(3) 5]

During 2006, about 21% of individuals in the European Union (27 countries) used the Internet to interact with public authorities.[(5) 5] Patients also search for information on medicines on the Internet more than before.[(6) 5] 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 product 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. In 2002 in a Communication to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions the Commission published quality criteria for health-related websites[(7) 6].

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

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6 Cf. Annex V of Commission Staff Working Document SEC(2007) 1740.

patients against agreed standards to ensure an appropriate level of quality in particular if this information is not originated from public authorities. There are however some Member States that have developed mechanisms such as internal procedures or self–control practices that could help information providers to improve the quality of information. In addition, keeping information on medicines on the Internet updated is a challenge for medicine authorities and other information providers.

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. Even if the internet technologies are constantly developed, for certain groups it can be difficult to access (e.g. the elderly) and there is a need the information available through traditional media means.

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. people with disabilities). 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.

2.3. Activities by the Commission and the EMEA

An overview of the activities developed by the European Commission and the EMEA, such as the information on medicinal products provided in the websites of Directorate-General Enterprise and Industry and the European Medicines Agency (EMEA), the activities of the EMEA with Patients' Organisations and the Health-EU Portal run by Directorate-General for Health and Consumer Protection, is given in Annex III of the Commission Staff Working Document.

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

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. (8) [7] They become intensely involved with their illness, show great interest in health issues and have a constantly growing need for information. (8) [7] Recent evidence indicates that patients are however often unsuccessful in playing a larger role in their health decisions. (9) [7]

Annex IV of the Commission Staff Working Document includes additional information on the evidence on patients' needs in terms of information and on the role of health professionals, patient organisations and partnerships, the pharmaceutical industry and the media.

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[7] Cf. Annex V of Commission Staff Working Document SEC(2007) 1740

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, the lack of detailed provisions concerning provision of information in Community legislation may lead to inequality in access for patients in the different Member States.

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.

4. SUMMARY AND CONCLUSIONS

4.1. Main findings on the basis of the report

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.(17) [8]

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.

4.2. Conclusions in view of public consultation responses

This Report on Current Practice with Regard to Provision of Information to Patients on Medicinal Products provides an overview of the current state of play and indicates issues to be addressed. The public consultation has provided an extensive set of contributions where views from the different sectors were expressed. A summary of the outcome of this consultation was published on the website of DG Enterprise and Industry's Pharmaceuticals Unit. The consultation responses have shown that the draft report reflected, apart from some factual details, the current situation. Nevertheless criticism refers to the lack of detailed impact assessment and to the depth of the analysis. While the limited number of factual issues and misunderstandings were corrected and figures were updated, the overall analysis was maintained with relevant clarifications added where appropriate.

Opinions expressed on the way forward converged as regards the needs to improve information to patients, to adopt common standards and quality criteria, to distinguish between advertising and information and to keep the ban on direct to consumer advertising on

[8] Cf. Annex V of Commission Staff Working Document SEC(2007) 1740.

prescription-only medicines, and the recognition of the Internet as an important information channel. Different views were expressed on how to improve provision of information to patients, on the role of the pharmaceutical industry and on the mechanisms to regulate and enforce applicable rules.

On the basis of the outcome of this consultation, the Commission intends to propose to the European Parliament and the Council amendments to the current rules on the provision of information to patients by the end of 2008. This proposal will put the interests of patients first and with this perspective should aim at reducing differences in access to information and should ensure the availability of good-quality, objective, reliable and non promotional information on medicinal products. The following main policy objectives will be pursued by this legal proposal:

(1) Establishing a framework which provides citizens of EU Member States with understandable, objective, high-quality and non-promotional information about the benefits and the risks of their medicines, and which maintains the confidence of citizens, regulators and healthcare professionals.

(2) Maintaining the ban on direct-to-consumer advertising of prescription medicines, making sure that there is a clear distinction between advertising and non-promotional information.

(3) Avoiding unnecessary bureaucracy, in line with the principles of Better Regulation

In accordance with Better Regulation practices the proposal will be substantiated by an impact assessment of the different policy options.