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COMMISSION STAFF WORKING DOCUMENT

Background information supportive to the 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 the form of different annexes.

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COMMISSION STAFF WORKING DOCUMENT

This document contains background information supportive to the 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 the form of different annexes as follows:

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Annex I: Political and legal framework

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

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"[1] 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"[2] 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 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

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1 COM(2003)383 final, 01.07.2003

2 OJ C 20, 24.01.2004, p. 2

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 to 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 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 Forum[3]. 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. Members have developed a

[3] http://ec.europa.eu/enterprise/phabiocom/comp_pf_en.htm

set of concrete deliverables which were in a public consultation in spring 2007 for comments and information.

The public consultation sought the views of the wider stakeholder society in particular on;

- a set of principles of quality of information and;
- a practical information model on a disease (diabetes), including treatment options

In addition to developing a draft diabetes information package and quality principles, the Information to Patients Working Group has also been looking at access to information in healthcare settings and examining the existing research on patient information needs and existing information tools available to the public. These documents and the individual responses sent to the public consultation together with a summary report can be found at the following website:http://ec.europa.eu/health/ph_overview/other_policies/pharmaceutical/results_consultation_en.htm

Following the public consultation and the second high level meeting of the Pharmaceutical Forum, the working group has been requested to continue its work in these areas to develop methodologies and concrete mechanisms to take work forward.

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 its final proposals and recommendations, following a public consultation, to the last High Level Pharmaceutical Forum which is due to meet in 2008.

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[4] and in Directive 2001/83/EC on the Community code for medicinal products for human use[5]. 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.

[4] 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.

[5] 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.

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.

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.

2.1 Detailed account of provisions in the legislation relating to advertising, information and, where relevant, transparency

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 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 provisions of Community law concerning the medicinal products.

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.

Further provisions of the pharmaceutical *acquis* which have a direct impact on information provided or made available to patients are summarised below.

2.2 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 Sates, 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).

2.3 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.[6] The EMEA currently prepares an assessment of this new mechanism on the basis of the 18 months of experience and feed back from users.

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

2.4 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 (NCAs) 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.

2.5 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, which are contained in articles 87, 89 and 90 of Directive 2001/83/EC, as amended. The relevant provisions are characterised

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

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.

2.6 Transparency measures

The current legislation provides for a number of transparency obligations in relation to the evaluation and supervision of medicinal products. Concerning the medicinal products subject to the centralised procedure and governed by Regulation (EC) No. 726/2004, these include, for example, making public information on the withdrawal of marketing authorisation applications (Article 11 and 36), distributing appropriate pharmacovigilance information to the general public (Articles 26, 47 and 57)or providing information on clinical trials through the *EudraPharm* database (Article 57).

Annex II: Information on Current Practices[7]

The following Table 1 indicates examples of Member States in accordance with the different practices which were identified:

Table 1: Examples of different patient information practices in Member States.

	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, NO, PT, SI, UK	AT, BE, DE, FR, NL, SE, UK

Concerning the different practices in Member States additional information as well as examples on best practices is provided in Tables 2 and 3 below.

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.(18)

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

[7] This information reflects the contributions received from the Member States at the date of preparation of this document, as a result of a consultation and as feedback after that. It may not fully reflect the factual situation, which may change rapidly.

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, the Medical Products Agency (MPA) is responsible for the NPL (Nationellt Produktregister for Lakemedel) system, which is a national repository (database) for medicinal products. The NPL data comprises information available in the information systems of the Medical Products Agency (MPA), the Pharmaceutical Benefits Board (LFN) and the retail and distribution pharmacy chain, Apoteket. Each organisation is responsible for the information it holds and that is transferred to the NPL. On the MPA website (www.lakemedelsverket.se/lakemedelsfakta), a product register search service, called Lakemedelsfakta, enables to search the NPL system. The system also links each product to its SPC, PIL and PAR documents.

www.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/), a nationwide portal service (http://www.terveyskirjasto.fi/terveyskirjasto/tk.koti) 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. Information on prices and reimbursements of medicines is available on the pages of the Social Insurance Institution of Finland (http://asiakas.kela.fi/laakekys_app/LaakekysApplication?kieli=en).

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.

In Germany, non-profit organizations such as the German Institute for Quality and Efficiency in Health Care (IQWiG) and the Agency for Quality in Medicine (AZQ) provide evidence-based patient information on medicines, treatments and other healthcare issues via www.gesunheitsinformation.de or www.patienten-information.de .

With reference to statutory information a website providing access to the statutory information on medicinal products offered by the DIMDI (German Institute of Medical Documentation and Information) is available. At the moment the 'Rote Liste' Service, run by pharmaceutical companies offers SPCs to health professionals only.

Table 2: Package leaflets, Summary of Product Characteristics and Public Assessment Reports available on the Internet in the EU Member States[8]

COUNTRIES				
	Package Leaflet	Summary of Products Characteristics		Public Assessment Report
		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	NO (under development)	YES	NO	NO (under development)
ESTONIA	**YES**	**YES**	**YES**	
FINLAND	**YES**	**YES**	**YES**	**NO (under develop.)**
FRANCE	**YES**	**YES**	**YES**	**YES**
GERMANY	**Yes**	**Yes**	**Yes**	**Yes**
GREECE	**YES**	**No**	**No**	
HUNGARY	**YES**	**YES**	**YES**	**NO (under develop.)**
IRELAND	**Yes**	**Yes**	**No**	**NO (under develop.)**
ITALY				
LATVIA	**YES**	**NO**	**YES**	
LITHUANIA				
LUXEMBOURG				
MALTA	**YES**	**YES**	**YES**	

[8] This information reflects the contributions received from the Member States at the date of preparation of this document, as a result of a consultation and as feedback after that. It may not fully reflect the factual situation, which may change rapidly.

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

Table 3- Examples of sources of information available on the INTERNET (Health authorities, Patients' organisations, pharmaceutical industry, public and/or private partnership).[9]

Country	INFORMATION AVAILABLE ON THE INTERNET				
	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,, www.kaypahoito.fi, www.terveyskirjasto.fi	Websites of patients' organisations, www.klik.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		www.dr.info.hu, www.doctorinfo.hu, www.weborvos.hu
Italy					

9 This information gives examples from the Member States at the date of preparation of this document, as a result of a consultation and as feedback after that. It may not fully reflect the factual situation, which may change rapidly and must not be regarded as a complete list of Member States' activities.

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), www.portalsaude.pt, www.dgsaude.pt
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 Authoriy website (www.mhra.gov.uk); Electronic Medicines Compendium (pharmaceutical industry); individual MAH websites	Competent authority (www.mhra.gsi.gov.uk)	NHS Direct Online, Electonic Medicines Compendium (pharmaceutical industry), Individual MAH websites, Patient Support Groups (various), www.informationprescription.info	www.medicines.org.uk
Liechtenstein		delegated to a company (www.documed.ch)	Not published		
Ireland	Electronic Medicines Compendium (pharmaceutical industry);	Competent Authority website (www.imb.ie), Electronic Medicines Compendium (pharmaceutical industry	Will be provided by the IMB, not yet available	Patients' organisations, individual MAH websites.	

	individual MAH websites s	www.medicines.ie); individual MAH websites			
Norway	www.legemiddelsiden.no	www.felleskatalogen.no, www.legemiddelsiden.no, www.noma.no		www.legemiddelsiden.no, www.noma.no	www.noma.no
Sweden	www.lakemedelsverket.se, www.fass.se	www.lakemedelsverket.se, www.fass.se	www.lakemedelsverket.se	www.lakemedelsverket.se, www.sjukvardsradgivningen.se, www.sos.se, www.sbu.se, www.lfn.se	www.apoteket.se, www.netdoctor.se
Denmark		www.produktresume.dk, www.dkma.dk		www.medicinmedfornuft.dk, www.sundhed.dk, www.sst.dk	www.medicinpriser.dk, www.interaktionsdfatabasen.dk
Germany	Website of DIMDI, www.pharmnet.bund.de, www.patienteninfo-service.de (under develop.)	Website of DIMDI, www.fachinfo-service.de, www.pharmnet.bund.de	Website of DIMDI, www.pharmnet.bund.de, www.hma.eu (for medicinal products on mutual recognition or decentralised procedure)	Ministry of Health, medicinal product agencies (BfArM, PEI), other authorities (DIMDI, RKI), consumer protection organisation (IQWiG)	BZGA, RKI

Annex III: Activities by the Commission and the EMEA

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

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 EMEA (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.

2. Activities of the EMEA with Patients' Organisations

Regulation (EC) No 726/2004 provides in its Article 78 additional responsibility to the EMEA to develop contacts with consumers and patients. In this context the EMEA has established in liaison with the Committee for Medicinal Products for Human Use (CHMP) the EMEA/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 EMEA/CHMP Working Group with Patients' and Consumers' Organisations" has been prepared[10].

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 EMEA/CHMP and Patients' Organisations;

3. Health-EU Portal

In addition to the work of the Pharmaceutical Forum, DG Health and Consumer Protection launched the Health-EU Portal[11] in May 2006. Its objective is to provide a trusted single point of entry for health-related information in all official languages. The Portal is designed to be comprehensive and easy to use, as well as providing citizens with the means to take individual

[10] http://emea.europa.eu/htms/human/patientgroup/PatientWG.htm

[11] http://health.europa.eu

action to improve their health. One of the key features of the Portal is that it introduces in a thematic way health issues at Community level. Each of the themes and topics are replicated across all the 27 Member States and EEA countries, and there are also comprehensive links to European NGOs and international organisations.

In order to address the issues related to quality and reliability of information, the Commission has set up an Editorial Board made up of Member States and other stakeholders, who agree an editorial policy for the Portal based on the best expert advice of members and in line with the eEurope 2002: Quality Criteria for Health related websites. The Portal follows the internationally recognised rules on accessibility for people with disabilities and older people.

Annex IV: The patient needs on the provision of information

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

Studies show that consumers are most keen on looking for information about adverse effects of medicines[10], the level of efficacy of certain products for certain diseases, the costs of treatments and the reasons for the prescription of a specified medicine. [11]

The available literature also suggests that the diversity of patients' needs cannot be underestimated.[12] The importance and relative priority of needs vary substantially between different types of patients. 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.[12]

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, 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 [13, 14].

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). [15]

Patient organisations themselves also have an important role as providers of information with a potential to increase over the coming years in the Member States.

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.(16)

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.(16) 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.(16)

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. 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.(17)

4. The role of the pharmaceutical industry

Pharmaceutical companies provide all the data required demonstrating the quality, safety and efficacy of medicinal products, namely pharmacokinetic and pharmacodynamic documentation they have collected from the drug development studies, including results from clinical trials, to regulatory authorities. It is also their responsibility to provide the pharmacovigilance related information and results from post-authorisation studies related to the safety, efficacy and utilisation of medicinal products. All this documentation is evaluated by drug regulatory authorities during the marketing authorisation process. Thus, 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.

5. The role of the media

Safe distribution of medicines to the public is a major public health challenge. Today, thanks to the regulatory framework which has been implemented in the European Union, the Union is one of the safest places to buy and use medicines. Since 1992 EU legislation has clearly differentiated between advertisement and information on medicines, but has not changed fundamentally in spite of societal changes (demographic changes and ageing, empowerment of patients) and technological development (Internet, treatment options).

The Commission is aware that while the regulatory framework differentiates information from advertising, in practice setting the borderline between what is an advertisement and what is a piece of information is a difficult task, while the situation may vary from one Member State to another. The Commission is also aware that media are in principle more easily accessible for all groups of citizens rather than the Internet, nevertheless the primary objectives should be to enhance consumer and patient protection, achieve better legal certainty and contribute to the efficiency of the internal market by eliminating inequalities between Member States. With these objectives the role of the media in disseminating high quality, verified information on medicines could be further explored.

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