

European Commission's modified legislative proposals on information to patients

EPF position statement

February 2012

The European Patients' Forum (EPF) welcomes the opportunity to comment on the European Commission's modified proposals concerning "information to patients" , which we see as a significant improvement on the original 2008 proposals. We believe that, while some concerns remain and would need to be clarified, they represent a step towards more equitable access of all patients across the European Union to high-quality information on medicinal products.

EPF was founded in 2003 to become the collective patients' voice at EU level, manifesting the solidarity, power and unity of the EU patients' movement. EPF currently represents 50 member organisations; disease-specific patient organisations active at European level, and national coalitions of patients' organisations. EPF reflects the voice of an estimated 150 million patients affected by various chronic diseases in the European Union, and their families. EPF facilitates the exchange of good practice, and challenges bad practice on patients' rights, equitable access to treatment and care, and health-related quality of life. Our vision is high quality, patient-centred, equitable healthcare for all patients in the EU.

Methodology of the EPF position statement

EPF has contributed to the debate on information to patients on a number of occasions in the last years, drawing upon a consultation of our European-wide membership. All previous contributions are available on EPF's website.² The current paper is based on a renewed consultation of the membership, together with input from EPF's Policy Advisory Group, and has been endorsed by the EPF Board. A full list of EPF's member organisations can be found on our website.³

Why this legislation matters for patients

EPF believes that all patients – no matter their condition, background or nationality – have a fundamental and legitimate human right to access information about their health, including their medical conditions and diseases and all available treatment options both

1

¹ Amended proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards information to the general public on medicinal products subject to medical prescription (COM(2012) 48 final); Amended proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 as regards information to the general public on medicinal products for human use subject to medical prescription (COM(2012) 49 final).

http://www.eu-patient.eu/Initatives-Policy/Policy/Pharmaceutical-Package/Information-to-Patients1/

³ http://www.eu-patient.eu/Members/The-EPF-Members/

pharmacological and non-pharmacological. It is a question of solidarity, equity and patients' rights.

The aim of information to patients must be to foster **patients' empowerment**, and enable them to take on an active role in their own health and healthcare. The EU Health Strategy, "Together for Health", recognises citizens' empowerment as a core value of European health systems and patients' rights as a starting point for Community health policy. The Council Conclusions adopted on chronic diseases in 2011 reiterate the importance of the fundamental values of universality, high-quality care, equity and solidarity, as well as the importance of reducing inequalities in health.

Access to high quality information is also, for patients, an important aspect of health equity. Currently, there are **unacceptable and unjustifiable inequalities** in patients' access to information on medicines across the EU, resulting from divergent interpretation of <u>Directive 2001/83/EC</u> by Member States. This problem is compounded by the **possibilities of the Internet**, which offers global access to uncontrolled, unverified information of varying quality in a matter of seconds, and can make it difficult to distinguish between good and bad quality information. Moreover, information is mostly available in English only.

European health systems need to embrace patient-centred healthcare to empower patients to become an active player in the co-management of his/her own health, instead of a passive subject. Such patients' empowerment will enable shared decision-making and effective self-management by patients, carers and families in close partnership with health professionals. Implementing patient-centred healthcare is, in our view, at the heart of ensuring the future sustainability and high quality of European health systems.

Access to quality information to patients together with improved health literacy, is in EPF's view a key strategy to equip patients to take on this role and to motivate patients to take more responsibility for their own healthcare.⁷

Patients call for a comprehensive EU strategy on information

Information to patients is not only about medicines, but an all-embracing approach to information, including therapies, self-management, quality of life, lifestyle, social and peer support, patient education and reimbursement options. EPF has repeatedly called for a comprehensive, EU-wide strategy on information to patients including (e-)health literacy. Well-informed patients are an asset to society. They take greater responsibility for their health and medical treatment, self-manage effectively, and use health resources in an optimal way. 9,10 In the context of the current challenges to the long-term sustainability of

⁴ White Paper COM(2007) 630 final, page 4.

⁵ Council conclusions 'Innovative approaches for chronic diseases in public health and healthcare systems' (2011/C 74/03).

⁶ For example: Wagner, E.H. Chronic disease management: What will it take to improve care for chronic illness? Effective Clinical Practice. 1998;1:2-4.

⁷ More information available on the "homepage" of the CCM at http://www.improvingchroniccare.org/index.php?p=The Chronic Care Model&s=2

 $^{^{8}}$ Explanatory statement of the report by Christofer Fjellner, MEP, 19 October 2010 (A7-0289/2010).

⁹ "Health Literacy – part 2: evidence and case studies", World Health Communication Associates, 2010, pp. 20-22. Available online at http://www.whcaonline.org/uploads/publications/WHCAhealthLiteracy-28.3.2010.pdf

European health systems, and the implications for patients, we feel this issue is more pertinent than ever.

EPF and our members therefore calls upon the Commission and other EU Institutions to work with stakeholders, including patient organisations, to formulate **a coherent, comprehensive and ambitious EU strategy** for patient-centred information, including health literacy, in order to complement the current proposals and support patients' and citizens' empowerment.

EPF's position on the Commission's modified proposals

Below we give EPF's comments on the key provisions in the Commission's modified proposals concerning information to the general public on medicinal products subject to medical prescription.

1. Obligation on industry to make available information

The amended proposals **introduce an obligation on marketing authorisation holders** to make available certain basic information to the public – namely, the most recent versions of the documents that are approved as part of the marketing authorisation process (the summary of product characteristics, labelling and package leaflet, and the publicly accessible version of the assessment report).

EPF comments

EPF welcomes this change, which effects a *crucial shift in focus onto the right of patients* to access high-quality, non-promotional information about medicinal products. This is in our view a provision of crucial importance to ensure access to a minimum level of basic information about medicines.

2. Additional information that industry may make available

The Commission proposes that the marketing authorisation holder could in addition make available certain other, limited, product-related information, once pre-approved by competent authorities.

EPF believes strongly that *the current ban on direct-to-consumer advertising of prescription medicines must be maintained*, but that marketing authorisation holders can be allowed to make available certain well-defined types of information through strictly limited channels, with verification and monitoring by competent authorities.

EPF comments

While EPF is broadly supportive of the types of information listed under Art.100b(2), we would like to make the following remarks.

Concerning point e, EPF believes that the publication of the results of all clinical trials –
including those that 'failed' or did not produce expected results ones – should be

¹⁰ "The costs of limited health literacy: a systematic review", Eichler K, Wieser S, Bruegger U, Int J Public Health, 2009;54(5):313-24.

obligatory on companies, and should be done through the European database on clinical trials¹¹ maintained by the European Medicines Agency, in a user-friendly, accessible and understandable format. Lack of access to the results of clinical trials decreases the willingness of patients to participate in trials. 12 At macro level, even trials that have failed can reveal important information.

- Concerning point b, patients would like more transparency concerning pricing of medicines.
- Concerning point f, patients would find summaries of frequently asked questions and answers very useful. To ensure the accuracy and reliability of the summary documents, companies submitting them for approval should be asked to include original copies of questions received and responses given, which they would in any case be required to keep on file for inspections.

Principle of pre-approval of information

EPF welcomes the *principle of pre-approval of information* by competent authorities, whilst also recognising that some Member States cannot implement such a system due to constitutional constraints, and should therefore be able to keep their own system.

We are, however, concerned regarding the timelines for pre-approval of information on centrally approved products, which would be the responsibility of the European Medicines Agency. If a large number of applications are submitted within a short time the Agency may not have sufficient human resources to be able to keep to the proposed time limit of 60 days. This would potentially result in too many automatic approvals and could affect the quality of the information.

EPF comments

We recommend that the European Medicines Agency be ensured adequate resources to undertake the task of pre-approval. We further suggest that for first-time approvals (of a "package" of information for a specific product) the timeline could be extended, while for reapprovals and updates the timelines could be kept shorter.

We stress the need for a harmonised set of criteria for pre-approval to ensure consistent quality of information and avoid fragmentation between Member States. EPF will be pleased to contribute to the development of criteria and guidelines at EU level.

Quality criteria for information

EPF welcomes the introduction of clear quality criteria (Article 100d), which broadly conform to the core quality principles developed by the High-Level Pharmaceutical Forum and endorsed by stakeholders and EU Member Stakes. 13 Quality criteria are absolutely key to ensure that information is objective, reliable, relevant and user-friendly. Such quality

¹¹ https://www.clinicaltrialsregister.eu

¹² Sood, A, Prasad, K & Wahner, L (2009), "Patients' Attitudes and Preferences about Participation and Recruitment Strategies in Clinical Trials", Mayo Clin Proc. 84(3) pp.243-247.

¹³ More information is available at http://ec.europa.eu/pharmaforum/information en.htm

criteria should, however, be applied to all information to patients – whether its source be industry or public authorities – to ensure that the information meets patients' needs.

EPF comments

EPF recommends that the *quality criteria should be applied to <u>all</u> information to patients, regardless of its source (i.e., also information originating from competent authority sources at national and EU level, or from non-profit organisations). We also recommend to <i>add the criterion of "relevance"*, as per the core quality criteria of the Pharmaceutical Forum: information should focus on issues that are of relevance and importance to patients' decision-making, such as risks/benefits, or adverse reactions. Finally, we recommend that *patients should be involved* in the production and dissemination of information wherever possible to ensure that the information meets the real life needs of users.

5. Information that is not considered advertising

Title VIIIa lists certain categories of information that are not considered advertising. EPF can support this list with certain caveats.

EPF comments

Information relating to human health or diseases: Companies could make available information on human health or diseases, provided there is no reference, even indirect, to individual medicines. EPF considers that the word "individual" could be confusing here, and may be better omitted. Generally, information on human health and diseases can be very helpful, as long as it can be trusted to be accurate. As long as the source is clearly identified, marketing authorisation holders can be a useful source of such information.

Information on vaccination campaigns: EPF welcomes the clear delimitation of this point and the criteria for approval of vaccination campaigns: competent authorities should approve such campaigns only when it is ensured that objective, non-biased information is provided on the efficacy, adverse reactions and contra-indications of the vaccine.

As above, quality criteria should be applied to information under this category. We also call for more effective use of already existing information resources developed by patient organisations in various disease areas. A key function of patient organisations at local, national and EU level is to provide information and support to their patient communities, and they should be appropriately supported in this function.

6. Channels for the dissemination of information

Information made available by industry for the public must *use clearly defined channels*, excluding newspapers, magazines or similar publications, radio and television. The proposals allow information to be made available only through

- Internet websites (excluding any unsolicited material actively distributed to the public);
- printed materials about a specific medicinal product, which can only be made available to the general public upon specific request or through healthcare professionals; and

• written answers to specific requests for information about a medicinal product from members of the public.

EPF comments

Given that patients already seek information from various sources, particularly the Internet which is global and unrestricted nature, EPF welcomes these provisions. They provide clear criteria for company websites that make available information to patients on prescription medicinal products. In addition, the inclusion of printed materials available upon specific requests is compatible with the "pull" principle to access information – that is, if a person proactively requests further information that person should be able to access it.

The provision concerning *written answers* is important to ensure that persons without access to the Internet or computers are able to access information. While in principle, printed materials would come under the pre-approval process, it would not be possible to pre-approve written answers to specific requests. However, companies would have to keep copies of all answers available for inspection by competent authorities.

Regarding material that can be given to patients by *healthcare professionals*, EPF is content that the proposal does not create any obligation towards health professionals to do so.

We would reiterate the importance of a good relationship and dialogue between patient and health professional, based on trust. Health professionals should remain the main source of information to patients. But in practice, health professionals often are not able to provide all the information patients need, at the time when they need it. Research shows that health professionals tend to overestimate the information they provide, and patients' understanding of it, while patients tend to want more information. A recent study showed a majority of patients diagnosed with cancer accessed information online; however, only a minority discuss with their doctor what they found. There is a need to reinforce the patient-health professional relationship, *inter alia* by implementing best practices in patient-centred healthcare, addressing barriers such as time and attitudes, and ensuring that health professionals' professional education provides them with the right skills to communicate effectively with patients.

7. Internet websites set up by companies

Citizens are increasingly using the Internet to search for health and medicines-related information, and therefore it is necessary to have easily identifiable, registered websites with objective and non-promotional information for patients. The amended proposals aim to create a network of Internet sources, whereby websites set up by marketing authorisation holders must be inter-linked with the relevant EU information portals maintained by the European Medicines Agency, as well as information websites or portals maintained by national competent authorities.

__

¹⁴ Coulter, A (2007) "Evidence on the effectiveness of strategies to improve patients' experience of cancer care", Cancer Reform Strategy Patient Experience Working Group. Available at http://www.pickereurope.org/Filestore/PIE reports/project reports/Cancer reform strategy Macmillan.pdf

¹⁵ Presentation "New Doctor-Patient Relations in Europe: Patient perspective", 22 June 2011, by Jan Geissler – Patvocates/Leukämie-Online/CML Advocates Network. Available at http://www.slideshare.net/Doctors20/workshop-9270049

Content of company websites

The websites must reproduce the statutory documents, and the source must be clearly identified. The information must comply with the quality criteria and contain additional statements regarding the registration of the website, pre (or post) approval of the information contained therein and the relevant links to EU and national web sources, but not to other industry websites. Updates of the content would be subject to approval. It is also made clear that individual members of the public cannot be identified, and unsolicited material cannot be distributed to the public.

EPF comments

EPF is satisfied that the conditions concerning the content of company websites are satisfactory. We believe that this system of interlinked websites, if well implemented and avoiding duplication can provide a user-friendly, high-quality information resources accessible equally by patients in all Member States in their own languages.

Registration of company websites

Websites set up by marketing authorisation holders to provide information to the public on their prescription-only medicinal products would need to be registered with a national competent authority. Once a site is registered, its contents could also be provided on other websites of the same marketing authorisation holder, provided that the contents are identical. Companies may select the Member State of authorisation in cases where a non-country-specific Top Level Domain¹⁶ is used.

EPF comments

We strongly recommend that the criteria for the registration of company websites should be harmonised to ensure they are equivalent across the EU. Binding guidelines to this effect should be developed at EU level.

8. Monitoring and sanctions

The responsibility for monitoring information made available through the websites will lie with that Member State where the website is registered. Member States are free to determine the mechanisms for monitoring and enforcement, but they should be effective. The modified proposals add the possibility to *publish the name of a company* that has made available information that is non-compliant (so-called "name and shame" punishment).

EPF comments

EPF is supportive of these provisions, however we are concerned that the *penalties should* be consistent and equivalent across all Member States. This could be addressed through developing common binding criteria. Member States have possibility to act if they have concerns about websites registered in other Member States.

We recommend that there should also be an effective *channel for patients and citizens* to bring cases to the attention of the national competent authorities and/or the European Medicines Agency, if they have concerns about any information they have accessed.

¹⁶ Country code Top Level Domains include for example: .co.uk, .au, .de

9. Other provisions

- The revised proposal provides that third parties, such as patients, patient organisations or the press, should be able to express their views on prescription medicines, and should therefore not be covered by the provisions of the Directive. To establish their independence from a marketing authorisation holder, all third parties must be transparent and declare any financial or other interests when making available information. This provision covers also healthcare professionals delivering information on medicines at public events.
- Information should be accessible for persons with disabilities
- Provision is made for appropriate consultation of relevant stakeholders.

EPF comments

EPF welcomes these provisions. We believe that a transparency requirement on third parties is reasonable and fair, while it acknowledges the need to safeguard fundamental freedoms of citizens – including civil society organisations and the media – to express their views. EPF as an organisation is fully committed to the principle and the practice of transparency, as reflected in our core values outlined in our Strategic Plan.¹⁷

Conclusions

The European Patients' Forum calls on the Council, the European Commission and the European Parliament to work together with stakeholders towards completing the revision of Directive 2001/83/EC with provisions for information to patients that help create a more equitable access to information across the European Union. EPF and our members are willing to enter into a dialogue with the European Commission, European Parliament and the Member States to ensure that the vision and core issues outlined in the Commission's proposals on information on prescription medicines can be translated into effective, patient-centred EU legislation.

We continue to advocate for a comprehensive strategy for information to patients, comprising health literacy, to complement the current one and build on the provisions of other recent pieces of EU legislation, such as those on pharmacovigilance and falsified medicines, and cross-border healthcare.

For more information visit www.eu-patient.eu or contact:

Nicola Bedlington Executive Director Tel. + 32 2 280 23 34

Email: nicola.bedlington@eu-patient.eu

Kaisa Immonen-Charalambous Senior Policy Adviser

Tel. +32 2 280 23 34

Email: kaisa.immonen.charalambous@eu-

patient.eu

¹⁷ http://www.eu-patient.eu/Doc<u>uments/AboutEPF/Howwework/epf_strategic_plan.pdf</u>