



HAI Europe
Jacob van Lennepkade 334T
1053 NJ Amsterdam
The Netherlands
Tel: +31 20 683 3684
Fax: +31 20685 5002
Email: teresa@haiweb.org
Web site: <http://www.haiweb.org>

Health Action International Response to the High Level Pharmaceutical Forum Public consultation on Health-related information to patients

Summary of key points

If the aim of regulation of pharmaceuticals and provision of information to accompany prescription medicines is improvement of public health, both the High-Level Pharmaceutical Forum and the Working Group on Information to Patients are of grave concern. The Pharmaceutical Forum follows on from the G-10; both advisory committees are heavily dominated by the pharmaceutical industry and appear to have an industry-driven agenda. Organizations without pharmaceutical industry funding, like HAI-Europe, have been largely excluded from this process.

These are the key points raised by HAI-Europe in its response to the High Level Pharmaceutical Forum consultation:

1. The Pharmaceutical industry has no role in providing the public with comparative information on drug treatments, or in the provision of information on disease epidemiology or prognosis. These are information needs that can only be met by information providers without conflicts of interest.
2. The opacity of the Pharmaceutical Forum, as well as the absence of any clear methodology resulted in an obscure process and poor quality outcomes.
3. The 'diabetes information package' which is being put forward by the Pharmaceutical Forum omits important information. It provides no useful information on disease reversal, prevention of progression, prognosis, complication rates, relative effectiveness of different treatments in preventing complications, common harmful effects of treatments, or serious adverse events.
4. The quality principles being proposed have serious shortcomings. They do not include any reference to conflicts of interest, are vague and do not take into account other instruments to measure the quality of health information that are already available, such as the United Kingdom's DISCERN^{i,ii} questionnaire.
5. Organizations and individuals with experience in providing health and medicines information to the public have not been consulted in the High-Level Pharmaceutical Forum.
6. The legitimacy of the initiative is open to question.

I. Diabetes Information Package

The process

The covering information with the consultation states: “The reason for preparing this information package was to test, for the first time at the European level, whether and how information on treatments could be developed based on a disease area in a partnership involving public authorities and key stakeholders - including the industry.”

The main aim of this initiative appears to be to involve the pharmaceutical industry in provision of health information to the European public. Following the failure of the attempt to introduce direct-to-consumer advertising for diabetes, asthma and HIV/AIDS in Europe in 2001 and 2002, pressure from industry has continued. This is despite an overwhelming vote by the European Parliament and Council against such an introduction.

The European Parliament asked the Commission to examine ways to improve provision of patient information in Europe. The parliament did not ask the Commission to examine ways to assist the industry in promoting its products to the European public. These favour the interests of the pharmaceutical industry over the interests of patients.

In fact, the amendment introduced in April 2004 clearly states

“the Commission shall, following consultations with patients’ and consumers’ organizations, doctors’ and pharmacists’ 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 and its risks and benefits for patients.”

The consultation process has been skewed towards aims other than the provision of the best possible information to meet patients’ needs. **HAI-Europe disagrees fundamentally with the way the consultation has been framed, both in terms of the types of questions asked and the manner in which the documents appear to have been produced.**

What information is appropriate at a European level?

If patient information needs were given priority, rather than the pharmaceutical industry’s needs, this information initiative would look very different. The following type of information would be helpful at a European level:

- Prevalence rates by age and sex for type 1 and type 2 diabetes, with a breakdown by country and region, including discussion of reasons for inter-country differences;
- Diabetes complication rates, with information on average timing and range of timing of expected complications from disease diagnosis for type 1 and type 2 diabetes (provided with a similar breakdown of data: per country, elaborating on explanatory factors for potential differences between countries);
- Links and/or references to accurate, independent, unbiased information from non-commercial information providers on the epidemiology and natural history of diabetes.

The latter should be provided by the European Public Health Executive Agency. There is no reason to involve the pharmaceutical industry or the medical device industry in disease prevalence data provision, nor on information on prognosis.

The European Medicines Evaluation Agency (EMA) could provide information on available drug treatments:

- What products have been approved in the European Union;
- Links to approved product information and European Public Assessment Reports (EPARs);
- Links to pre-market drug evaluations complete clinical trial information concerning all drugs approved through the centralized or decentralized procedures, and any reviews of diabetes drugs carried out by the Committee of Medicinal Products for Human Use (CHMP), since the EMA came into existence in 1995;
- Comparative pricing information between products and countries;
- National and European safety advisories on diabetes products;
- Links to sources of independent, unbiased comparative information.

Why is this information package unacceptable?

The diabetes information package has many hallmarks of ‘disease-mongering’ and product promotion.

Specifically the paper promotes a view of diabetes that inevitably leads to intensive progressive drug treatment which it need not be. This is consistent with a ‘disease-mongering’ approach promoting anxiety in patients rather than accurate, balanced, unbiased information:

- Diabetes disease progression is presented as an inevitability;
- Complications are discussed without any framing that might allow a person with a new diagnosis to know how likely they are to develop each one;
- No information is provided on disease prevention or prevention of progression as a viable option instead of drug treatment;
- The distinction between type 1 diabetes, for which insulin replacement is necessary, and type 2 diabetes, for which drug treatment may be avoided with adequate dietary and lifestyle changes, is blurred;
- No information is provided on the proportion of people with a type 2 diabetes diagnosis who are able to manage their condition without drug treatment. In contrast for instance the US Centers for Disease Control states that 15% of US patients with a type 2 diabetes diagnosis do not use any medications.
- The need for statins and anti-hypertensives is presented as inevitable in addition to drugs to control blood glucose. This fails to take into account the difference between different patients’ situations and differences in risk for future cardiovascular events. In patients who are at low risk for cardiovascular complications, harm from additional drug treatments may outweigh benefits.

In terms of the treatments that are discussed:

- Treatment benefits are presented as assured and harms are not discussed, which is in general consistent with the type of bias expected from an industry information source;
- No information is provided on harmful effects of any product being referred;
- No comparative information is provided that might help a reader to avoid certain products without clinical trial evidence of benefits in terms of prevention of complications, such as the glitazones;
- No information is provided on the degree of expected benefit from medication use, such as the proportion of complications prevented over a specific information;
- Phrases such as ‘your physician will chose the type of insulin that is best for you’ are highly patronizing and make a mockery of the suggestion that patients should be involved in self-management;
- No information is provided on serious harmful effects that have led to legal actions, such as inadequate glycaemic control experienced by some type 1 diabetics when they have been switched from animal to human recombinant insulins or heart failure associated with glitazones.

The diabetes information package is not a rigorously developed consumer information brochure. It would rate very poorly using the DISCERN instrument: no explicit aims, no individual authors, no date, no identification of areas of uncertainty, no description of benefits/risks of treatments, etc.

Specific questions addressed within this consultation:

- 1. How useful is it to have this kind of concrete information at the European level on a disease and its related treatment options? If useful, what other diseases would benefit from this approach?**

It is not useful to provide information on diseases and their treatments within a private-public-partnership involving either the pharmaceutical or medical device industry or any other industry that has a product to sell to patients. There is a fundamental conflict of interest in such an approach.

Patients and the public need information that is independent of any need to promote product sales. The health industries cannot meet this need as no company can be expected to paint its own product in an unfavourable light, to paint competitors’ products in a more favourable light, or to explain to the public how to best avoid use of its products.

Companies play a vital role in producing pharmaceutical treatments and diagnostic devices. Provision of approved product information, within patient information leaflets, could be much improved. Similarly, access to unpublished clinical trial and drug safety data could be much improved. These are appropriate roles for pharmaceutical companies and the improvement of the quality of information required under the Law is an important goal for the industry.

No role exists for the industry in providing the public with comparative information on drug treatments, nor in provision of unbiased information on disease

epidemiology or prognosis. These are information needs that can only be met by providers without conflict of interest.

People facing a new chronic disease diagnosis are in an extremely vulnerable position. They need access to unbiased independent comparative information that has been designed with their involvement, in order to meet their needs. They do not need access to information that has been designed with industry involvement in order to meet industry's need for a competitive advantage.

2. Which elements of this diabetes information package are the most/least useful? Which elements are missing and should be included?

It is impossible to see any added value for this information package for patients in Europe beyond many different types of information that are already available. The package provides no useful information on disease reversal, prevention of progression, prognosis, complication rates, relative effectiveness of different treatments in preventing complications, common harmful effects of treatments, serious adverse events. It does not provide any of the basic information needed for patients to make informed treatment choices. No comparative information is included on drug treatments and no drawbacks of drug treatment are mentioned.

3. Which elements of information in the diabetes information package should be provided at the national level (by national authorities for example)?

The diabetes information package does not provide useful information for the public. National governments may want to provide information on disease epidemiology, prognosis, and strategies to reverse an early diagnosis and avoid disease progression. They could finance consumer and health professional organizations to produce accurate, unbiased comparative information that answers questions identified both by people with a disease diagnosis and the public at large. Such organizations must be completely independent of any industry that produces products of any sort for disease prevention, treatment and diagnosis, including drug and device manufacturers.

4. How this kind of information package should be developed further at national or European level?

This package fails to meet public or patient information needs and the initiative should not be pursued or expanded. There is a European Union role in information provision. The European Public Health Executive Agency could provide both pan-European information on disease epidemiology and comparative information between countries. DG Sanco and EMEA could jointly provide comparative information on availability and prices of different treatments and could provide easy links to approved product information in a centralized location, including patient information leaflets, EPARS, reports such as pre-market drug reviews that form the basis for regulatory decisions, post-market regulatory documents including Periodic Safety Update Reports (PSURs), safety advisories etc.

II. Quality Principles

The quality principles have serious shortcomings. Again, there is no clear indication of the process, or of the methods used to produce this document. The authors have failed to identify existing resources for appraisal of health information. For example, quality criteria for consumer information have already been developed in several countries, including in the United Kingdom with the DISCERN instrument, in Australia with the recommendations developed by the National Health and Medical Research Council (NHMRC)ⁱⁱⁱ and the guide published by the Victorian Government on communicating with consumers^{iv}. Inevitably, if it is judged necessary to have a set of quality principles at the European Union level, they should be developed in a professional manner and take into account other previously available relevant resources.

The set of quality criteria does not contain detailed background information which would allow patients and consumers to verify whether information brochures are compliant with these principles. For example, there are no checklists included. It is not a user-friendly approach. Its application also remains vague and provides extensive 'wiggle room' for manipulation of content.

Specific questions raised as to the quality principles:

1. Is a set of principles on good quality information on health-related information and treatments for patients and citizens useful at the EU level?

In theory it would be useful to have a set of quality criteria applied to existing information sources, which would allow the EU Commission, its bodies and agencies, to direct the public to useful sources of information and help them to avoid disguised promotion of various sorts.

However, the current set of principles fails to ensure information quality. They also fail to take into account or make any reference to previously developed information quality criteria (see for example DISCERN in the UK or the criteria for Cochrane collaboration systematic reviews of the effectiveness of medical treatments and interventions).

If the diabetes information package has been produced on the basis of the quality criteria as outlined, there is a serious problem with these criteria. No information is provided on the methods employed or the quality criteria applied. There is no indication of any kind of systematic review of the research literature, review methods, or criteria used to judge the strength or weakness of the research evidence. No comparative information is provided on prevention or treatment options. The strength of any information quality criteria can be best judged in their application. As the diabetes information package is the first example of the application of these criteria, the criteria themselves are highly problematic. Not a single harmful treatment effect is mentioned. The poor quality of the information is so extreme that it indicates there is a major problem with the whole process.

2. Do these principles provide a clear basis on which to judge the quality of information at a European level?

No, not at all. It would be beneficial to develop public education on critical appraisal of health information. Most notably, such a programme/initiative could be provided as a

guide to Member States, so that they would be able to develop their own culturally sensitive and adapted information/education. This would inevitably also promote greater health literacy. **Despite arguments in contrary, there is a wealth of information available^v, what the patients and general public often lack are the skills, training and experience evaluate it and distinguish promotional material from unbiased information.**

3. Should any of these principles be revised and if so, how? Are there any important principles missing?

A key principle that is missing concerns conflicts of interest. The quality of patient information on diseases and medical treatments is dependent on an absence of conflicts of interest. There should be no involvement of any industry with a product to sell for disease, diagnosis, treatment or prevention.

ⁱ The DISCERN instrument. Available at <http://www.discern.org.uk/>

ⁱⁱ Charnock D, Shepperd S, Needham, G and Gann R. DISCERN: An instrument for judging the quality of written consumer health information on treatment choices. *J. Epidemiol. Community Health* 1999; 53: 105–111.

ⁱⁱⁱ NHRMC. How to present the evidence for consumers: preparation of consumer publications. Canberra 1999. Available at <http://www.nhmrc.gov.au/publications/synopses/cp66syn.htm>

^{iv} Currie K, Spink J and Rajendran M. Communicating with Consumers Series Volume 1. Well-written health information: a guide. Department of Human Services Victoria, July 2000. Melbourne, Victoria. Available at <http://www.health.vic.gov.au/consumer/pubs/written.htm>.

^v Joint declaration by HAI Europe, the ISDB, BEUC, the AIM and the Medicines in Europe Forum "Relevant information for empowered citizens" 3 October 2006: 9 pages. Available at Website: <http://www.haiweb.org/01102006/PatientInformationDeclaration.pdf>

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