



## **European Heart Network's response to the European Commission's draft report on current practice with regard to provision of information to patients on medicinal products – Brussels 19 April 2007**

*June 2007*

### **I Introduction and information**

The European Heart Network (EHN) is a Brussels-based alliance of heart foundations and likeminded non-governmental organisations throughout Europe with member organisations in 26 countries.

EHN plays a leading role in the prevention and reduction of cardiovascular disease through advocacy, networking and education so that it is no longer a major cause of premature death and disability throughout Europe.

Cardiovascular disease is the number one cause of death among women and men in Europe. It accounts for almost half of all deaths in Europe causing over 4,35 million deaths each year in the member states of the World Health Organization (WHO) European Region (52 member states) and more than 1,9 million deaths each year in the European Union(25). Cardiovascular disease is also a major cause of disability and a reduced quality of life. Cardiovascular disease is estimated to cost the EU economy €169 billion/year. CVD cost the health care systems of the EU just under € 105 billion/year is cost to the. Production losses due to cardiovascular disease mortality and morbidity cost the EU over €35 billion and cost of informal care is over € 29 billion/year.

Below EHN will comment on the European Commission's draft report on current practice with regard to provision of information to patients on medicinal products (the report), discuss sources of information of medicinal products as well as delivery mechanisms.

## II Primary information on medicinal products

### 1. *Pharmaceutical industry*

As stated in the Commission's report, pharmaceutical companies possess key information about their products. In fact, they are the only ones to have all the information of any one product. In general, however, only part is made available to patients, e.g. through leaflets and labels.

## III Delivery mechanisms of information to patients

### a) **International and European level**

#### 1. *Internet and other technologies - General*

Internet is a widely used source of information for consumers and increasingly patients also search information on medicines from the Internet. Use of internet varies according to age, education, gender and socio-economic conditions.

The Internet is a powerful tool. However, there are issues concerning the Internet, not least when it comes to information on diseases/medical conditions and medicinal products. Such issues include reliability and quality of the information; accessibility, including age, level of education and price; the fact that the information is of a general nature; and the sheer mass of information.

#### 2. *Websites – specifically European Commission and EMEA*

The website of the European Commission's (EC) *Pharmaceuticals Unit of Directorate-General Enterprise and Industry* provides information on medicinal products, notably through the Community Register of Medicinal Products. This register comprises a list of all products authorised by the Community.

The approved information about all the medicinal products authorised by the EC is published on the website of the *EMEA*. The information on the EMEA website includes terms and conditions of the authorisation, the summary of product characteristics, the patient information leaflet and the labelling. EMEA's EudraPharm database, launched on 6 December 2006, currently contains information on products authorised at Community level in accordance with regulation (EC) 726/2004. It will include summary of product characteristics, the package leaflets and the labelling of medicinal products worded in an appropriate and comprehensible manner for the general public. According to the Commission, this database will be a central tool to make existing product specific information available to health professionals, patients, regulators, industry, other interested parties and the general public.

In May 2006, the *Directorate-General Health and Consumer Protection* launched the EU Health Portal. Its objective is to provide a trusted single point of entry for health-related information. It is designed to provide information on a wide range of health-related topics to citizens, patients, health professionals, regulators and policy makers. It seeks to provide the European citizens with a comprehensive and easy-to-use tool to access information and to take individual action to improve their health.

From the description in the report, EHN is not entirely clear how these websites interact and, particularly what is the main difference between the contents of the EMEA website and its EudraPharm database. EHN supports the paper's suggestion to ensure synergies between the EU Health Portal and the EudraPharm (and other approved) database(s). Information about citizens' use of and evaluation of these websites/databases would be of interest.

### 3. *Package leaflets*

Medicinal products marketed in the EU have to include a package leaflet containing information intended for and relevant to the patient. Package leaflets must be worded in an understandable way and be subject to consultation with target patient groups to ensure readability.

#### **b) National level**

##### 1. *Health professionals*

The report states that health professionals are the primary conveyer of health information, particular on treatments and medicines and that a proactive dialogue between physicians and patients is essential. The report also states that other health professionals, including nurses and pharmacists, are very important in conveying information to patients.

##### 2. *Patient organisations and health charities*

Patients' organisations and health charities are traditionally providers of health information to patients and the general public.

EHN's member organisations are specialised in cardiovascular diseases, particularly coronary heart disease and stroke. EHN's member organisations provide information on these diseases, their risk factors and how to prevent the diseases. They also provide information on available treatment and guidelines for treatment, including use of certain groups of medicines. The information is available on-line and in brochures. All information is provided in easy-to-understand language. EHN member organisations do not provide information on individual medicinal products.

### *3. Medicines' regulatory authorities*

In some Member States, the provision of information on medicines is mainly ensured by public authorities and includes predominantly information on products that they have approved. Other information may be treatment guidelines or comparative information on the value of medicines.

### *4. Public Private Partnerships (PPP)*

There are a wide range of PPPs across the EU. They provide information on medicines and/or information on disease management (for health professionals) and, in a special brochures, for patients). Such PPPs may include public authorities, pharmaceutical industry, doctors, pharmacists organisations and patient organisations.

### *5. Pharmaceutical companies*

The pharmaceutical industry is not allowed to advertise medicinal products that are available on prescription only to the general public. Pharmaceutical companies can answer specific questions about a particular product by providing factual and informative announcements and can provide general information on human health and diseases without reference to a particular product.

## **IV Conclusions and recommendations**

It follows from the report that a number of delivery mechanisms of information to patients, and indeed the general public, exist across the EU. It also follows that citizens across the EU have unequal access to information due to a) diverse legislative frameworks; b) levels of education and technological skills; c) knowledge of languages.

The report states that lack of Community legislation currently hampers equal access to information. Only one rule is clear: advertising of medicinal products that are available on prescription only to the general public is prohibited.

Information on conditions and diseases, prevention and treatment is widely available from numerous sources and via numerous mechanisms. Information on medicinal products is also available from numerous sources; mechanisms include health professionals, national and European databases, PPP bodies and pharmaceutical companies.

EHN believes that:

- patients have the right to obtain as much information as possible about their conditions, diseases, possibilities for prevention and treatment, medicinal products and their availability
- information to patients must be reliable, unbiased, understandable and of the highest quality
- national PPP bodies or platforms can be important sources of information to patients on medicinal products.

EHN recommends that:

- health professionals should remain the primary source of health information, particular on treatments and medicines and that a proactive dialogue between physicians and patients is essential and must be promoted. EHN believes that other health professionals, including nurses and pharmacists, also are very important in conveying information to patients. EHN notes that this dialogue is particularly important in providing the patient with individualised information on their conditions, the medicinal product(s) that has(have) been chosen for them including possible side-effects, possible alternative medicinal products and interaction with other medicinal products that the patients take
- package leaflets as appropriately regulated should remain an important source of information to patients. Further testing for readability is needed and reference to an approved website for more information (see below) could be added to the leaflets
- national platforms should be independent of pharmaceutical industry, and ideally financially independent, but the pharmaceutical industry could be a member alongside patients organisations, health charities, health professional organisations and public authorities. The platform should draw its information from public medicines regulatory bodies' websites and databases; the EC's and EMEA's websites and databases; and should be in a position to request information from pharmaceutical companies that is in their possession but not otherwise available. The platform should make all information, as validated by its members, available to the public electronically and otherwise
- a quality mark should be considered for websites that provide information on diseases, prevention and treatment; it must be ensured, though, that obtaining the quality mark is not unnecessarily burdensome from an administrative point of view
- the public is informed about the national platforms as the authoritative and best source of information on medicinal products; the public is educated about the need to trust information only from websites with the quality mark

- the EU should set quality standards for the provision of health information and information of medicinal products (these should be the basis for information provided by national platforms and for awarding the quality mark)
- direct to consumer advertising of prescription only medicinal products must continue to be prohibited.

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