April 2008

Cancer Research UK's response to a European Commission (DG Enterprise) consultation on Information to Patients

Introduction

Cancer Research UK[1] is the world's largest independent organisation dedicated to cancer research, with a research spend of over 415 million euros in 2006/07. Our vision is that together we will beat cancer. We carry out world-class research to improve our understanding of cancer and to find out how to prevent, diagnose and treat different types of the disease. We ensure that our findings are used to improve the lives of all cancer patients.

Cancer Research UK is the European leader in the development of new anti-cancer treatments and the largest single funder of cancer research in Europe.

We welcome the opportunity to respond to the consultation.

Cancer Research UK's role in information provision

Cancer Research UK's vision to beat cancer includes helping people to understand the disease and the choices that each person can make. Our long term goal is to ensure that all cancer patients in the UK are able to access the information they need at diagnosis, during and after treatment. To help meet this goal we provide a range of information resources in the UK including:

- **CancerHelp UK:** this is the charity's patient information website. It contains information developed specifically for the web on all types of cancer, treatment and issues related to living with cancer. It also includes a unique database of clinical trials written in plain English. The site is the most popular UK cancer site, with around 3 million pages viewed per month. All material for the website is written by experienced cancer nurses with additional skills in plain English writing. New sections are checked by two independent cancer experts before being added to the website. The site is updated daily with developments in cancer care as well as annual formal review for each section.

- **Cancer information phone service:** this is a confidential free phone service staffed by qualified nurses. All the nurses have at least three years cancer nursing experience and have ongoing training and education to make sure they keep right up to date with developments in cancer treatment and care. Along with answering questions about cancer and its treatment the nurses help people to understand and cope with the emotional impact of being diagnosed with cancer. The nurses respond to around 10,000 enquiries per year by telephone, email and letter.

- **National cancer awareness and prevention campaigns:** we run several national awareness campaigns. One such example is 'Reduce the Risk' which aims to raise public awareness of the avoidable risks for cancer and the importance of early detection.

[1] Registered charity no. in UK 1089464.

- **Cancer Statistics:** Our CancerStats reports include detailed analysis of UK, European and world cancer statistics and information on risk factors, symptoms and treatment.

- **Information prescriptions:** Cancer Research UK is partnering with Cancerbackup and Macmillan Cancer Suport to develop information prescriptions for patients diagnosed with cancer. The project, part of a Department of Health funded pilot initiative, is being rolled out across the UK in 2008. The aim of the project is to ensure that high quality information products and resources will be more easily available to cancer patients. One of the projects under this scheme is the roll out of audio cancer information cassettes to support the UK's half a million people with print disabilities who are affected by cancer.

General Comments

It is our understanding that the proposals outlined in the Commission's paper aim to ensure that all patients in the EU have equal access to good-quality, objective, reliable and non promotional information on prescription-only medicinal products. While this aim is laudable we have several concerns regarding how the Commission proposes to meet this objective.

Equal access to information across Europe

While we recognise that not all patients in the EU have access to the same level of information on medicinal products (as highlighted in the Commission's 2007 report '*Current practices with regard to the provision of information to patients on medicinal products'*), we question whether liberalising the current restrictions on prescription-only medicines will improve this situation.

The current EU legislative framework does not hamper equal access to information. In our view problems arise from the fact that countries have interpreted the rules differently. This situation could be further exacerbated as pharmaceutical companies may only choose to focus on Member States with large markets and relatively large healthcare budgets leaving patients in smaller Member States no better off than under the current legal situation/regime.

We believe that the Commission should instead focus on ensuring that information in the Patient Information Leaflets (PILs), already translated into the various EU languages is more easily accessible to patients and consumers.

The scope of the consultation

While aware of the division of competencies within the European Commission, such that DG Enterprise and Industry having responsibility for pharmaceutical products and DG SANCO for overall health issues including the EU Health Portal, we question whether the approach proposed in the paper to only focus on prescription-only medicines, is the most appropriate way to ensure that patients in the EU have access to the necessary information on their condition and treatment options.

The issue of information to patients is broad and should not be confined to one aspect of information provision, that of prescription-only medicines.

Specific comments on the proposal

Objectives and impact assessment

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

We question whether this objective will be met by the means suggested in the paper. It is unclear how, or if, pharmaceutical companies can and will provide non-promotional information. Also, in light of previous activities by the pharmaceutical industry, it is also questionable whether they would, in practice, provide full information on the potential risks of their medicines. With no prior vetting of the information foreseen in the 'framework', as proposed, it is doubtful that 'the confidence of citizens, regulators and healthcare professionals' would be maintained.

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

We support the maintenance of the ban on direct-to-consumer advertising of prescription medicines. However we are concerned that the Commission's proposal with its weak distinction between information and advertising would, in fact, open the door to direct-to-consumer advertising (DCTA) in the EU.

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

While in general we support the avoidance of unnecessary bureaucracy, we question whether the principles of Better Regulation should be applied in this instance. The aim must be to ensure that any information provided to patients or consumers is reliable, of high quality and independently verified.

Key ideas for the forthcoming proposal

3.1. Provisions on advertisement: The current rules ban advertisement of prescription medicines to the general public. At the same time they allow advertisement of over the counter medicines. These rules should not be changed.

We agree with this point.

3.2. Scope, content and general principles of the new legal provisions: The revision should clarify the rules on information provided by pharmaceutical companies on prescription-only medicines. Communication not covered by the definition of advertisement, should be regarded as information. Clear criteria should distinguish the information that is allowed from the information that is not allowed.

Information should be compatible with approved summaries of product characteristics and patient information leaflets, and it should not contradict or go beyond the key elements specified in them.

Other limited medicine-related information could also be given (information about scientific studies, prevention of diseases such as vaccines, accompanying measures

to medical treatments, prices). In addition, specific quality criteria should be defined and respected.

The distinction between information and advertising is very unclear. The paper refers to 'clear criteria' however only a general outline of these criteria is given in the paper. Also, the paper does not clearly explain which body or organisation would verify that information provided by the pharmaceutical industry does not go beyond what is given in the Summary of Product Characteristics (SPCs) or PILs.

Further clarification is needed with regards to 'scientific studies etc'. Is the Commission referring to independent studies or studies undertaken by the company producing the medicinal product?

3.3 Type of actions, content and monitoring of information: A distinction should be made between the cases where the patient is passively receiving the information ("push") or actively searching for the information ("pull") in terms of the monitoring mechanism.

It is unclear why the Commission makes this distinction. All information, either passively received or sought, should conform to the same high quality standards.

3.3.1 Information passively received by citizens: Under the clear safeguard that all advertisement to the public is banned, it should be possible for the pharmaceutical industry to disseminate information on prescription-only medicines through TV and radio programmes, through printed material actively distributed, through information in printed media or through audiovisual and written material provided to patients by healthcare professionals. To facilitate the monitoring of the information provided, a mechanism should be set up to ensure that the information providers inform national co-regulatory bodies about their activities before action is taken.

The distinction between disseminating information via TV and radio and advertising is very unclear and could be viewed as contradicting paragraph 3.1 which maintains the ban on advertising of medicinal products.

The recently amended EU Directive 2007/65/EEC on Audiovisual Media Services specifically prohibits product placement of medicines on television. We strongly urge the Commission to maintain the current legal situation with regards to the provision of information on prescription-only medicinal products.

3.3.2. Information searched by citizens: Further, when industry disseminates information on prescription medicines through Internet websites or verbally, it should announce such information activities to a national co-regulatory body which should monitor the contents without validating ex-post or exante specific actions.

It is unclear how national co-regulatory bodies will be able to monitor all the information distributed by industry, in particular verbal information.

3.3.3. Answering requests from citizens: Citizens often have questions to pharmaceutical companies. Replies by industry to enquiries from citizens through written solicited posting or e-mail should be monitored based on complaints.

It may be difficult for members of the general public to assess the quality of the information being provided. Also it is unclear to which body or organisation a patient or consumer would register a complaint and how that complaint would be followed up.

4. Quality criteria

All information provided to citizens should fulfil specific criteria concerning the quality of the information. The information provided should be objective and unbiased, patient oriented, evidence-based, up-to-date, accessible, transparent, relevant and consistent with approved information. Comparisons between medicinal products should not be allowed.

Although we agree in principle, it is not clear what organisation/body would verify that all information meets the above criteria, and indeed who this organisation or body would be accountable to.

5. Proposed structure for monitoring and sanctions

Each Member State could set-up a **national co-regulatory body**, consisting of public authorities and a mix of stakeholders, including healthcare professionals, patient organisations and the pharmaceutical industry. These co-regulatory bodies could be responsible for ● adopting a code of conduct on information to patients; ● monitoring and following up of all information activities by the industry.

We would like to draw attention to the fact that in the UK, 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. This is housed on NHS Direct Online and linked to independently authored, non-promotional Medicine Guides for individual generic and branded products.

This scheme also covers prescription only medicines for all therapeutic areas. We believe that the Commission should continue to help Member States exchange best practice on national schemes and consider developing a European version of this type of scheme.

Conclusion and suggestions for alternative action

We urge the Commission ***not*** to change the current situation regarding the provision of information on prescription-only medicines by the pharmaceutical industry. We stress that the Commission should consider the issue of information provision to patients in a holistic manner and not solely focus on one aspect.

We recommend that the Commission:

➢ **Retains the strict ban** on direct to consumer advertising (DTCA) therefore keeping Article 88, paragraphs 1 and 3 of Directive 2001//81/EC as amended by 2004/27/EC unchanged.

Instead we suggest that the Commission focus on the following activities:

➢ Allocate the appropriate funding to speed up the creation of the **EudraPharm – database** on medicines authorised in the EU.

➢ Ensure that the EudraPharm database is linked with other existing instruments e.g. a link with the **EU Health Portal** run by DG SANCO.

➢ Continue to facilitate the **sharing of best practice** between Members States.

For further information or clarification on any point raised in this response, please contact the Cancer Research UK Public Affairs Department on publicaffairs@cancer.org.uk or on +4420 7 061 8360.