



HEALTH COMMUNICATIONS COUNCIL

Submission to the Consultation regarding a legal proposal on information to patients

Brussels, 4 April 2008.

The Health Communications Council (HCC) of the European Association of Communications Agencies (EACA) welcomes and supports the Commission proposal to envisage the possibility to allow information to the public via pushed media as well as on internet websites for medicinal products and prescription medicines.

EACA HCC Objectives

The Health Communications Council is composed of senior managers from the top 5 communications groups in the world. Our members represent companies that are working on a day to day basis in communicating health information to doctors, patients and other stakeholders. As such, the HCC can be considered experts in Healthcare Communications in Europe

1) Patients need more and better information and education

1.1 Lack of awareness of symptoms of major diseases

Because of a lack of information, patients often do not recognize symptoms of major diseases such as diabetes or life-threatening diseases such as cancer and tend not to consult their doctor at a time when the disease can be fully cured.

Diabetes

The British Diabetic Association published a study¹ to quantify the effect of an advertising campaign on the awareness of symptoms of diabetes among the general public.

The study was based on the observation that patients often have symptoms for prolonged periods before they consult.

The advertising campaign lasted 10 weeks and included posters displayed in all shopping precincts and other pedestrian areas in the two towns participating in the research as well as in the local press twice a week. The advertisements were designed to present the symptoms of diabetes in a factual and clear manner. 3000 people between 25 and 75 years, excluding people with diabetes and health professionals, were interviewed. 43 general practices were monitoring the numbers of patients who would specifically request tests to exclude diabetes.

¹ B.M. Singh, J.J.W. Prescott, R. Guy, M. Murphy, P.H. Wise "Effect of advertising on awareness of symptoms of diabetes among the general public: the British Diabetic Association Study", BMJ; 308:632-636, March 1994



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The advertising campaign raised the public's awareness of diabetes symptoms, although the effect varied between symptoms. The number of patients who specifically requested tests for diabetes grew by 70% during the 10 week advertising period and among these there was a high diagnosis rate for diabetes.

Cardiac arrest

Researchers from the National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, published the results of a survey they conducted in 14 states to assess the level of public awareness of the signs of myocardial infarction (heart attack).

They asked respondents to identify "the five signs and symptoms of a heart attack" from a list of six symptoms and then asked the respondents what they would do if they believed they or a loved one were having a heart attack.

Only 32% could identify all five signs of a heart attack and only 27% could identify all five signs and knew which public telephone emergency number to call.

Hepatitis C

In England 200,000 people have hepatitis C, the majority of whom are unaware of their condition. This illustrates the importance of raising awareness of the virus. Symptoms that may be experienced include fatigue, muscle aches, alcohol intolerance and pain over the liver.

1.2 Patients often incorrectly comply with prescribed drug use

Patients with chronic conditions requiring daily intakes of medication when they do not feel ill or even unwell often do not take their prescribed medication regularly. Such diseases where medication can be critical include for example LDL cholesterol, hypertension or post-menopausal osteoporosis.

In life-threatening diseases such as transplantation (of liver, heart and kidneys) patient non-compliance rates vary from 20% to 50%. More precisely, reports² indicate post-operative immunoprophylaxis non-compliance from 3% to 36% and appointment non-compliance after transplantation between 3% and 79%. This results in major problems for the patients which can range from rejection of the transplant to the patient's death.

Methods that have been found to improve compliance or adherence to medication are: patient education, improved dosing schedules, increased hours when the doctor is available or clinic is open, improved communication between physicians and patients.

² Lars Osterberg, M.D., Terence Blaschke, M.D., "Adherence to Medication", New England Journal of Medicine 353;5, 4 August 2005



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2) Patients can access information regarding prescription medicines via US websites

Today, European patients as long as they understand English, have no difficulty whatsoever to access all information to patients regarding prescription medicines on US websites. This puts non-English speaking European patients at a distinct disadvantage and the information provided corresponds to US legal requirements rather than European legislation. Two examples of easily accessible webpages are the Xenical³ pages by Roche, and Symbicort⁴ by Astra-Zeneca.

3) A need for a precise definition of advertising in Europe

The current definition of “advertising” in the directive on a Community Code on medicinal products for human use is excessively broad and covers more or less any activity undertaken with a commercial intent. It does not correspond to advertising but rather to marketing.

Article 86 – of the current directive

1. For the purposes of this Title, ‘**advertising of medicinal products**’ shall include any form of **door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:**

- **the advertising of medicinal products to the general public,**
- **advertising of medicinal products to persons qualified to prescribe or supply them,**
- **visits by medical sales representatives to persons qualified to prescribe medicinal products,**
- **the supply of samples,**
- **the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal,**
- **sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products,**
- **sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.**

In order to clarify the debate, the EACA HCC would like to **propose the following definition** for what constitutes advertising (as opposed to information):

- **Advertising of prescription medicines is any representation made to the public via media⁵ with the clear intention of selling a specific medicinal product sold on prescription**

³ > <http://www.xenical.com/> <

⁴ > <http://www.mysymbicort.com/symbicort/how-symbicort-works/symbicort-right.aspx> <

⁵ Media includes all print media such as newspapers or magazines, posters, television and radio, cinema and the internet.



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4) The need for a precise definition of information to patients

Assuming that the above definition proscribes advertising to patients, we would like to propose the following definition of information to patients which could be allowed:

- ***Information to patients about prescription medicines is any information given to the public via media⁶ with the clear intention of improving the understanding of the conditions for use, dosage and eventual side-effects of a specific medicinal product sold on prescription within the context of a particular disease***

The HCC would like to reiterate the parameters according to which any information to patients should be judged, as expressed in its submission⁷ made in 2007:

- 1) Information must communicate well to the average patient – not all patients are well educated,
- 2) It is scientifically accurate – this is imperative,
- 3) It complies with the requirements of the national future co-regulatory bodies.

This would reorganise qualitative criteria for information to patients listed in the consultation paper in the following order:

- 1) Relevant, accessible and patient-oriented,
- 2) Evidence-based and up-to-date,
- 3) Consistent with approved information,
- 4) Objective and unbiased, transparent.

Please find some examples of unbranded campaigns based on information to patients for diseases in the ANNEX. Currently we cannot provide examples of branded campaigns based on information to patients for prescription medicines as these would be illegal.

5) EACA HCC agencies have established effective processes differentiating information/education activities from promotional activities

All big Healthcare Communications Agency Networks members of the HCC have already integrated effective processes to allow the differentiation of promotional activities from educational/informational activities. Although these processes are currently used for communication with doctors, they can easily be adapted for communication with patients.

⁶ Ibid footnote 5

⁷ Submission to Draft report on current practice with regard to the provision of information to patients on medicinal products, 1 July 2007



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6) Supervision of information

The role of national co-regulatory bodies composed of public authorities and stakeholders will be to define Codes of Conduct and to monitor their application. In order to be applicable and effective, the clarity of wording of such Codes will be essential.

Therefore the members of HCC believe that, as communication experts who are faced with the challenge to express complex and highly technical issues in a simple and clear manner on a daily basis, their active participation in those co-regulatory bodies is key to obtaining effective Codes.



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ANNEX

Examples of information to patient campaigns

Campaign to raise awareness about cardiovascular diseases

Agency: Strategic&Numeric
Advertiser: Pfizer

1982
Coup de foudre

1982 2006
Foudroyé

En France,
1 décès sur 3
est lié à une maladie
cardiovasculaire⁽¹⁾.

1 sur 3 : ça peut être vous, votre conjoint ou votre meilleur ami.
Vous avez plus de 40 ans ? Pour savoir si vous devez consulter votre médecin traitant afin d'évaluer
votre niveau de risque cardiovasculaire, faites des maintenant le test ci-dessous :

| | | | |
|----------------------------|--|------------------------------|------------------------------|
| CONSULT-QUIZ-CARDIO | • Vous fumez ou avez arrêté de fumer depuis moins de 3 ans. | OUI <input type="checkbox"/> | NON <input type="checkbox"/> |
| | • Un membre de votre famille a eu une attaque cérébrale avant 45 ans. | OUI <input type="checkbox"/> | NON <input type="checkbox"/> |
| | • Il est survenu une crise cardiaque ou une mort subite chez votre père ou votre frère avant 55 ans ou chez votre mère ou votre sœur avant 65 ans. | OUI <input type="checkbox"/> | NON <input type="checkbox"/> |
| | • Le résultat du calcul suivant est supérieur à 20. votre poids (en kg) \times votre taille (en m) Ex: vous pesez 80kg et mesurez 1m70 80 - 32 = 48 1,72 x 1,72 = 2,96 | OUI <input type="checkbox"/> | NON <input type="checkbox"/> |
| | • Sédentaire : vous faites moins de 3 fois 30 minutes d'exercice physique par semaine. | OUI <input type="checkbox"/> | NON <input type="checkbox"/> |

*1 seul "OUI" doit déjà vous alerter.
La crise cardiaque ou l'attaque cérébrale ne préviennent
pas toujours. Mais elles ne frappent pas non plus au hasard.
Consultez votre médecin traitant.
Avant qu'il ne soit trop tard.*

**Mon bat pour moi
je me bats pour lui!**

1. Programme national de réduction des risques cardiovasculaires 2002-2005.
Ministère délégué à la santé, 2002.

NSRF
Netherlands Scientific Research Foundation

Fédération Française
de Cardiologie

Pfizer

www.prevention-cardio.com



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Campaign to raise awareness that diabetics must stay under 7 in their quarterly hemoglobin test A1C

Agency: Euro RSCG Life
Advertiser: Sanofi

**Vous êtes diabétique ?
Retenez**

Et soyez en dessous...

**... Et vous,
faites-vous contrôler votre A1c ?**

Pour plus d'informations, parlez-en à votre médecin
ou appelez au **0811 88 7777** (coût appel local)

Alfediam
Fédération Française des Diabétiques et des Malades Métaboliques

en partenariat
avec

Aventis

Association Française des Diabétiques

Message de l'Association Française des Diabétiques et des Professionnels de Santé de l'Alfediam en partenariat avec l'Institut Aventis.



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BMI Disease awareness campaign – 3 page leaflet recto/verso

Agency: McCann Healthcare Worldwide

Advertiser: Roche

Is your weight loss plan not working?



You are not alone

In fact, almost half the adults in the UK have a problem with their weight.

Being overweight can make all kinds of everyday things harder to do. You might find that you don't enjoy sports so much anymore. Running around with your children, or grandchildren, can become increasingly tiring. Just walking to the shops may leave you breathless. Or climbing the stairs may make your joints ache. As well as slowing you down, some of these symptoms can be the first signs of a more serious health problem such as:

- High blood pressure
- High cholesterol
- Arthritis
- Severe snoring and disturbed sleep (sleep apnoea)
- Angina (chest pain due to exertion)
- Diabetes

But, losing just a bit of weight, and keeping it off, can seriously reduce the risk of these health problems and improve your overall well-being.

Losing weight isn't easy, but you can do it!

One of the best ways of losing weight is to reduce your fat intake, but it's hard not to give in to temptation. On top of that, food labelling can be confusing, and recommended portion sizes are often unclear. It makes it difficult to know just how much fat you're really eating.

Increasing physical activity is another good way of losing weight, but it's often hard to find the time, or difficult to know which sort of exercise is the most appropriate.

However, all your efforts to reduce your weight are really worth it. You'll feel better and healthier. But don't think that you need to change your whole lifestyle all at once. Start to make small changes - take it a step at a time, that way it will be easier to stick with the changes you make.

You may already be trying to be more active and to eat healthier food but still finding it hard to lose weight. So you'll be pleased to discover...

...there is more you can do in addition to lifestyle changes.

Your doctor can really help

Being overweight can cause serious health problems. If you have tried, unsuccessfully, to lose weight and keep it off, your doctor is the best person to advise you about losing weight safely and healthily. After all, he or she is not only interested in making people better, but also in preventing them from becoming unwell in the first place.

In addition to providing advice about all the different options available, your doctor can now also prescribe effective treatments if one of them is right for you. These aren't miracle treatments – but they can make a big difference if you combine them with healthy eating and exercise plans. Some of these treatments also involve free support programmes, which can be a big help with your weight loss.

Your doctor can only prescribe you a weight loss treatment if you are considered to be medically overweight. You can use the chart below to see if you may be suitable. Simply find your height and weight on the chart and see which of the coloured zones you are in. Then tick any of the boxes that apply to you.



Are you finding it hard to lose weight?

Have you tried many different ways to lose weight?

Do you feel depressed about your weight?

Do you lack energy?

Do you easily become breathless?

Do your joints sometimes ache?

Do you have diabetes, high cholesterol, or high blood pressure?

Do you feel your weight restricts what you can do?

Do you need to lose inches from around your waist?

Are you in the red zone?

If you are in the red zone and you've ticked any of the other boxes, you should take this leaflet and talk to your doctor. If you are serious about losing weight but finding it difficult, he or she will be able to help.



Go on, make an appointment today. You can make it happen.

For general health inquiries, call the **NHS HELPLINE 0800 22 44 00**

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