Response to the European Commission consultation regarding the legal proposal on information to patients

The British Medical Association is the UK's leading voluntary professional association and trade union of doctors with approximately 139,396 members which corresponds to around 68% of practising doctors in the UK.

We welcome the opportunity to contribute once more to the debate on patient information and to continue our engagement with EU policymakers on the issue.

The BMA strongly supports the provision of information to patients, particularly those suffering from chronic diseases. A well informed patient with a proactive interest in the management or treatment of their illness is beneficial to all involved in the treatment process.

From the outset, the BMA believes that it is important to reiterate its strong opposition to the direct to consumer advertising of prescription-only medicinal products. Such advertising encourages the medicalisation of social problems and plays on people's fears of suffering and death. The consequences of permitting direct to consumer advertising are all too evident in the US system where doctors are under pressure to prescribe according to drugs that patients may have seen on television rather than according to clinical need, and where prescribing patterns can be based on the basis of skilful advertising rather than on appropriateness and cost. The primacy of the dialogue between healthcare professionals and patients must be safeguarded, and protected from the potentially damaging impact of misinformation, and misdirected information.

Having said this, the BMA fully recognises the very real shortcomings in the current legislative framework as exists under article 88a of Directive 2001/83/EC and are concerned about the many discrepancies in information provision that exist between member states. These are highlighted in the European Commission report on current practices with regard to the provision of information to patients on medicinal products.

In line with both the European Commission and the pharmaceutical industry, the BMA has serious concerns over some of the information that is currently available to the public, particularly on the Internet, and would question the veracity and the evidence base for many of the claims that are made on unregulated websites. However, we do not believe that the proposals contained in the consultation document are a suitable response to this problem, nor do we believe that relaxing the rules on the provision of information by the pharmaceutical industry will eradicate the problem of misinformation.

This paper will now outline the BMA's principle concerns with the proposals contained in the consultation document before suggesting potential alternatives.

Distinction between information and advertising

The BMA believes that no clear distinction is made in the proposals between information and advertising. If information is allowed to be transmitted on television and radio in the UK, it will be contained in advertising slots on the commercial television channels. The public will have difficulty in distinguishing between promotional material and unbiased, evidence based information. The content of these information campaigns can overstate the benefits of a drug

and omit important elements such as price and side effects. Even if they do not overstate the benefits they will understate the contraindications and the real alternative treatments.

If the details provided on medicinal products via the media are truly information as opposed to advertising, we would suggest that no poignant images of human beings, no emotive music, no celebrity endorsements and no claims as to the effectiveness of the product may be used. The information must only convey appropriate parts of the patient information leaflet (PIL).

For print and Internet information campaigns, adequate safeguards must be in place to ensure that publications do not overstate the benefits of a drug. The BMA would like to see prominent warnings on all information provided by the pharmaceutical industry, similar to that on financial products, which would clearly state that *"This information has been produced by the pharmaceutical industry. More detailed information is available via your health practitioner."*

The BMA would also call for the generic name of the particular drug to be displayed prominently and in the same font size as the brand name. This is in an effort to inform patients of the various names of the drugs which they may be prescribed and to prevent them from insisting upon being prescribed a particular brand name as they are unable readily to discover information on the generic version.

The protection of patients is paramount and it is imperative to avoid the legalisation of clever marketing campaigns that will serve to misinform and confuse patients. In this respect, the BMA is concerned over the proposal to allow pharmaceutical companies to provide information on scientific studies, the content of which is not specified in the proposal. Many experienced health professionals have difficulty in critically appraising this information and the pharmaceutical industry is frequently criticised for its lack of transparency and selectivity in the publication of scientific data[1].

Financial impact of proposals

Reviews of direct to consumer advertising in New Zealand and the US have found that advertising is raising prescription costs. The studies also found that money is being spent overwhelmingly on profitable lifestyle drugs and squeezing expenditure on drugs that help genuinely ill people[2]. In the US especially, fears are growing that such campaigns are distorting health priorities by stimulating demand for pharmacological treatments for lifestyle conditions that may have better alternative treatments such as diet or exercise. Thus mass media information campaigns may encourage companies to focus on developing blockbuster drugs for prevalent but non-life threatening conditions to the detriment of other, less profitable drugs for which there is a genuine clinical need. The BMA fears that pharmaceutical companies will use similar techniques in their European information campaigns with the resulting impact on drug development and research for less profitable products.

This view is further developed when one considers that the provision of information will be most profitable for new, expensive drugs whose long term benefits may not yet be known and which have no established advantages over cheaper or generic alternatives or even over the counter drugs. Newer drugs are not necessarily better. If the rules on information provision are relaxed in the EU, drug companies are likely to spend most money promoting new, expensive and patent protected drugs which will create the most profit, thus undermining patient confidence in similar, cheaper yet just as effective drugs. To prevent this

[1] BMJ 2004;329:816, BMJ 2005;330:113, BMJ 2004;329:809-810
[2] BMJ 2005;330:5-6

situation from arising, the BMA would call for the imposition of a 'cooling off period' where new products can not be featured in an information campaign until they have been widely used by the general public for a specified period of time and after which the true effectiveness and full side effects will be better understood.

Information campaigns financed by the pharmaceutical industry will also increase health costs. Pharmaceutical companies need adequate returns on costly information campaigns thus the burden is shifted to the taxpayer through increased drug costs. The result will be that national healthcare resources will have to be diverted from treating patients in order to cover the increased cost of drugs. The full financial impact of this must be explored in greater depth before any decision is made to relax the rules on information provision.

Role of the co-regulatory bodies

The BMA believes strongly that in the event of a relaxation of the current rules on information to patients, a strict regulatory regime must be established. This must have a well defined legal framework which will examine all of the information provided by the pharmaceutical industry before it is published. It must also have the power to censure companies who publish information that does not meet the strict, pre-defined conditions as defined by an independent, peer reviewed advisory board comprised of health professionals and patient representatives.

The current proposals for national co-regulatory bodies as outlined in the consultation document fall well short of these conditions. The BMA is particularly concerned that the co-regulatory body would only be able to view the information post hoc, i.e. after it has been viewed by the public. This is unacceptable. There is a risk of abuse by some pharmaceutical companies who might publish inappropriate information in the knowledge that it will be viewed by and will influence the general public before eventually being removed. We are also worried that the co-regulatory body appears to have no defined legal powers with which to police the pharmaceutical industry and to protect vulnerable patients from misinformation.

The proposal to monitor direct communication between industry and patients "based on complaints" is not an adequate safeguard to protect vulnerable patients who may not be able to distinguish between information and advertising and may not have the technical knowledge to know that they are being misled. All direct correspondence between a pharmaceutical company and a patient must be submitted to the co-regulatory body for review.

Alternative suggestions

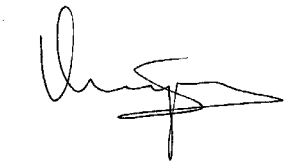
As stated above, the BMA supports the provision of information to patients and welcomes the opportunity to harmonise and regulate the quality of information available to European citizens. The BMA believes that this information should be provided by independent sources, in a transparent and high quality manner and free from commercial interest.

We support the creation of an Internet portal, provided by the European Commission or another such independent body, which would provide information to European patients. The information contained on this website must be of the highest possible quality and it is imperative that the information is free from undue industry influence. All information must be peer reviewed by an independent advisory board comprised of health professionals. The information could be accompanied by a kite mark which would enable patients to identify it as being high quality, objective information.

An independent European body of health professionals, patient groups and representatives of the pharmaceutical industry could produce a document, translated into all of the official

languages of the EU, which would list all of the drugs currently licensed for marketing in the EU and containing detailed information on their use and side effects. Such documents already exist in certain member states, most notably in the UK and Sweden.

In conclusion, whilst the BMA fully supports the need to provide information to patients on pharmaceutical products, we believe that the current legislative proposals do not provide adequate safeguards to protect patients from misinformation at best and from manipulation at worst. We believe that the proposals are premature and, in their current form, potentially dangerous to EU patients. The BMA calls for a more balanced discussion to take place before the European Commission puts forward plans to alter the current legal framework.



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