This response was submitted to the consultation held by the Nuffield Council on Bioethics on *Medical profiling and online medicine: the ethics of 'personalised' medicine in a consumer age* between April 2009 and July 2009**.** The views expressed are solely those of the respondent(s) and not those of the Council.

Medical profiling and online medicine – the ethics of 'personalised healthcare' in a consumer age

Response from the British Medical Association

General

The scope of this work is extremely broad covering a wide and diverse range of complex issues. Reading the document it is unclear what issues the Council is seeking to address although, following discussion with Hugh Whittall, we understand that the main focus is on the implications of individuals being encouraged to take more responsibility for their own health at a time when health products and services are increasingly becoming available on a commercial basis. This is an interesting and novel topic which merits consideration and is likely to stimulate debate. It is difficult from the consultation document, however, to identify the key themes or imagine how the final report will look. As it stands the consultation appears to seek general views on a wide range of diverse issues rather than using those issues to address a common theme. In addition, it is unclear how telemedicine fits into the work described by Hugh Whittall over the telephone. Some thought may therefore need to be given to reducing the scope of the work in order to make it more focussed.

This lack of a central focus in the document makes the consultation difficult to respond to. This problem is exacerbated by the wording of the questions, many of which are not only confusing but also seem to be seeking both personal experiences and more philosophical reflection. We have, however, attempted to answer the questions in a way that we hope will be helpful.

INTRODUCTION

Question 1 – Health care as a consumer good

If an increasing number of medical products and services are becoming available as consumer goods – that is to say, as commodities which customers may choose to purchase provided they can meet the costs – is this development, on balance, desirable?

If yes, in what ways do you think the positive consequences outweigh the negative ones?

If no, in what ways do you think the negative consequences outweigh the positive ones?

It is too simplistic to provide a "yes" or "no "answer to this question. The private provision of healthcare is a complex area covering a diverse range of issues and circumstances, each of which would merit detailed consideration. For example:

- People opting to pay for private treatment that is available within the NHS because they want more choice, more convenience, more comfortable surroundings or for other reasons.
- People opting to pay for treatments or services that are not available on the NHS – whether because the drug or treatment is considered to be too costly or not sufficiently cost-effective to be provided by the NHS, or because the individuals do not meet eligibility criteria, such as for NHS provision of IVF treatment.
- People opting to pay for purely elective procedures such as cosmetic surgery.
- Direct to the public private provision of tests for those who are at-risk of a particular disorder.
- Direct to the public provision of screening/health checks for the apparently healthy population

- Internet prescribing

Within each of these different scenarios there will be a range of factors that will affect whether their development is desirable or not. The acceptability or otherwise of particular services provided direct to the public, for example, will depend upon factors such as:

- The evidence-base supporting the treatment/testing that is offered
- The knowledge and experience of those providing the service/treatment
- Safeguards in place to ensure that the testing/treatment/drug is safe and appropriate for the individual
- The accuracy of the information provided about the service and the opportunities provided for those seeking treatment/testing to think through the issues.
- The level of on-going support available for those seeking treatment or testing who receive unexpected information about current or future illness
- The implications of the test to be carried out and of the information that will be provided.
- The extent to which individuals are encouraged to involve their GP.
- The consequences of apparently abnormal results to the individual and to state provided services. We are aware that, for example, CT/MRI scans of a large percentage of well people will show some abnormalities which must then be followed up to exclude disease. This follow-up is costly and may produce risks to the patient.

Question 2 – Validity of information

While much health related information is freely available to individuals, this varies greatly in quality and accuracy. Many of the lifestyle and health books and magazines that are currently available may contain medical information that is misleading or even incorrect from a scientific point of view. Do you think that information provided by DNA profiling and body imaging services raise different questions and should be subject to different regulations?

If yes, what are the grounds for restricting access to DNA profiling and body imaging services that may also have limitations in terms of scientific validity and clinical value

If no, why do you feel that DNA profiling and body imaging should be freely available to those who wish to receive it? Would you favour regulation of the information appearing in lifestyle and health books and magazines? And, if so, what sorts of information in particular require regulation?

This question is very confusing. It does not appear to relate to the preceding text and also mixes up two issues: regulation of the way information is provided and restrictions on the provision of services. It also questions whether there should be regulation of both the provision of information by service providers and information provided by magazines, in books etc. In the latter case while bodies like the BMA have a responsibility to provide information to try to ensure that accurate information is provided, it is difficult to see how this could be regulated. The question does not reflect the fact that many people gain accurate and reassuring information in user-friendly form from TV and magazines, which detail real cases of patients. For example, well-managed story lines in TV soap operas can be an effective way of raising awareness of health issues such as cervical screening and organ donation.

It is clear that if an organisation is providing services to the public there is both a legal and ethical responsibility to provide accurate information. Complaints about inaccurate and misleading information can be addressed by the Advertising Standards Authority or through civil action in the courts.

Although it is unclear, the question may be seeking views on whether it is legitimate to restrict companies from offering services where they do not meet specified levels of scientific validity. This is a difficult question to answer since some procedures which do not have a sound evidence base are nevertheless perceived to be beneficial by those who use them (including some forms of complementary medicine). A relevant consideration is the level of harm people may be exposing themselves to. If there is no evidence of benefit but equally no, or minimal, risk of harm, and the individual has been provided with accurate information then it is difficult to justify restricting access.

Some forms of complementary medicine are subject to voluntary or statutory regulation and this may be an issue that requires further consideration in respect of other direct to the public medical services. There is, however, the complicating factor that some providers of services, although accessible to UK citizens, are not based in the UK and therefore fall outside the remit of regulatory bodies including the Care Quality Commission.

Question 3 Prevention

Many governments argue that every individual has some responsibility to look after their own health, in their own interest and that of society at large, for instance in matters of lifestyle and diet. Do you think such individual responsibility should extend to the use of DNA profiling and body imaging services such that people in some circumstances should be expected, encouraged or obliged to have such tests?

If yes, what are those circumstances, and what should be the nature of such encouragement (for example: information, persuasion, financial incentives?)

If no, do you think there are other, more appropriate ways in which people can take personal responsibility for their health and, if so, which? In cases where early diagnosis of disease and subsequent preventive action can reduce later costs of treatment, but people choose not to find out whether they need to take preventive action, is it acceptable that the higher costs for later treatment are paid for by taxpayers or those contributing to health insurance schemes?

It is not only governments but also health organisations that encourage patient responsibility in terms of smoking, drinking etc which impact heavily on society at large. As a society, however, we do not oblige people to have testing or treatment, even where there are very serious implications for themselves or others. Both legally and ethically competent adults are entitled to refuse any test or treatment even if that results in their death. There are no grounds for treating DNA profiling or body imaging differently from any other form of testing or treatment in this respect.

Although a lot of the document is about the commercialisation of healthcare, we assume this question relates to NHS provided services given that it is not possible to oblige someone to have a test that is only available privately. If a test is clinically indicated it should be offered within the NHS. Individuals should be given information about why the test is being offered and the benefits of having it. If there are significant benefits they may also be encouraged to be tested but they are, and should be, free to withhold consent if that is their wish. In reality, most people accept the tests or treatment recommended by health professionals. If patients refuse there would usually be a discussion about the reason for the refusal, to ensure they have understood the information and are not basing their decision on misinformation but they would not be pressured to accept. There is no reason why the situation should be any different with DNA profiling or body imaging.

The BMA has very strongly argued against any suggestion that if people do not have tests that would enable them to prevent disease, they should be considered responsible for their condition and therefore less deserving of state funded healthcare. Everyone is aware of the health risks of smoking, being overweight, not exercising, excessive drinking etc but we do not refuse necessary healthcare to those whose conditions may have been preventable had they addressed these issues earlier. Nor should we. We should not impose greater responsibilities on those who have a genetic predisposition to disease than we do on other members of society.

Question 4 Who pays?

Many DNA profiling and body imaging services are paid for privately by the individual. However, positive findings may lead the individual to seek publicly funded services for follow-up diagnosis and treatment. Should public services be expected to fund such follow-up?

If yes, under what circumstances should such funding be provided? (For example: in all cases, only if the tests meet certain criteria, only for certain conditions?)

If no, should publicly funded health care services impose fees for such follow-up diagnosis and treatment (for instance by charging patients or by levies on private providers of body imaging and DNA profiling)?

Clinically indicated tests or treatment should be provided to those who are eligible for NHS treatment irrespective of how the problem was identified. Having the test does not cause the problem and earlier diagnosis can frequently be of significant clinical benefit. Those who seek diagnosis or testing privately, either through direct to patient services or through a referral to a private hospital, retain their entitlement to NHS treatment for any health problems identified. If, however, the GP does not consider that further tests or treatment are necessary they are not obliged to provide a referral. There are concerns that GPs will see increasing numbers of patients who do not have a health problem but who are anxious following private testing where the information provided and/or post-test support is inadequate (the so-called "worried well"). Such patients will need to be given reassurance.

ELECTRONIC HEALTH RECORDS

Question 5 Your experience

Have you used online health recording systems such as Google Health?

If yes, what led you to do so and how would you evaluate your experience? Which aspects did you like especially, which ones did you dislike?

If no, what factors would influence your decision whether or not to use such services in the future?

This question is not relevant to the BMA but the Association is supportive of patients having easier access to their healthcare records and having control over the extent to which their information is shared.

Google Health and Microsoft HealthVault provide one portal to manage care including access to records, managing prescriptions and finding more information about conditions. As the consultation mentions these services are available, almost exclusively, within the United States. This is not surprising given the way in which healthcare is managed in America. In the UK the patient's general practitioner maintains a single record of the individual's health profile and Healthspace has now been developed to allow patients to view their NHS Summary Care Record online. It is too early to judge how popular this service will be and whether there will be any demand among UK patients for a more comprehensive, private health records system. Whatever system is used, confidentiality is a key requirement. This must include protections against alteration or deletions by "hackers" and an audit trail identifying those who have accessed the file.

ONLINE HEALTH INFORMATION

Question 6 Your experiences

Have you used online sources for diagnostic purposes, for instance those provided by government agencies, patient groups, commercial companies or charities?

If yes, which services have you used, what led you to do so , and how would you evaluate your experience? Did you find the service useful in providing the information you were looking for, leading to better care or empowering you when talking to healthcare professionals? Or did it have some negative effects?

If no, under what circumstances if any would you consider using such services in the future?

This question is not relevant to the BMA but the Association is supportive of patients taking more interest in their own healthcare and having access to good quality, accurate health information. The BMA is, however, concerned that patients have no way of identifying which of the plethora of websites offering medical advice provide accurate, reliable and authoritative information. There are some websites that are very good (such as www.nhsdirect.nhs.uk and www.besttreatments.org) but others which look professional and authoritative are in fact promotional websites aimed at selling products. In its response to a recent EU consultation on information for patients (see enclosed) the BMA supported the proposal for an internet portal, provided by the European Commission or other such independent body, to provide information to patients. Any such resource would need to be of the highest possible quality, peer reviewed, understandable, accessible, transparent and reliable. Ideally it would be "kite marked" to enable patients to identify it as being high quality, objective information.

ONLINE DRUG PURCHASES

Question 7 Your experiences

Have you purchased prescription drugs over the internet?

If yes, what led you to do so and how would you evaluate your experience (for example, in terms of convenience, facing risks of obtaining the wrong or poor quality drugs, lack of medical supervision etc)?

If no, under what circumstances if any would you consider doing so for yourself or a relative or friend?

This question is not relevant to the BMA but we have some views on this issue which may be of interest. The BMA has expressed serious concern about the risks posed to the public through the ungoverned and unfettered availability of prescription drugs through the internet. Even where doctors are involved there are concerns where medication is prescribed without being able to verify the individual's identity or examine or question the patient. For this reason the BMA's General Practitioners Committee has advised that, other than for issuing repeat prescriptions, drugs should not be prescribed as a result of an on line consultation[1].

The General Medical Council's guidance on remote prescribing (http://www.gmc-uk.org/guidance/current/library/prescriptions_faqs.asp#5j) sets out a number of steps that must be taken to ensure patient safety if online prescribing takes place. This is, however, only binding on doctors who are registered in the UK whereas a large number of such companies are based overseas where there is less, or less rigorously enforced, regulation.

The BMA's annual meeting in 2007 called for better regulation of internet prescribing although we recognise that this is very difficult to achieve in practice. Some progress has been made over the last few years, with the MHRA reporting successes in terms of closing websites and prosecuting UK-based companies who are selling prescription-only medicines via the Internet and the introduction of the Royal Pharmaceutical Society of Great Britain's logo scheme. Nevertheless, to be truly effective any regulation needs to have a high level of international co-operation and regular enforcement activity.

Although the MHRA provides information for the public about the risks of purchasing prescription medication via the internet, some people are keen to use this option for the reasons mentioned in the consultation. The National Audit Office reported in 2003, for example, that 1% of the public it surveyed had purchased prescription-only medicines over the internet, saying it was the easiest way to obtain the medicine and that it cost less than with a prescription.[2] The most common drugs purchased were for obesity, erectile dysfunction, prostate disorders and hair loss. The BMA's own

[1] General Practitioners Committee. Consulting in the modern world – guidance for GPs. London: BMA, 2001.
[2] National Audit Office. Safety, quality, efficacy: regulating medicines in the UK. London: The Stationery Office, 2003 (HC 255)

work on cognitive enhancements[3] in 2007 also identified a small, but growing, trend for drugs such as Ritalin to be purchased by healthy individuals via the internet.

Question 8 Advertising health care products

Do you think it should be permissible to advertise prescription drugs direct to consumers.

If yes, should there be no restrictions whatsoever? Do you think that it should equally be acceptable to advertise DNA profiling or body imaging services direct to consumers (which are currently not prohibited in the UK)?

If no, what are your main concerns? Are you confident that access to drugs via GPs is a better alternative, ensuring that you will always receive the drug that is best suited to your specific condition? Do you think that advertising DNA profiling or body imaging services should equally be restricted or prohibited?

The BMA is strongly opposed to prescription-only medicines being advertised direct to the public. Such advertising treats potent medicines as simply another consumer product and adversely influences the discussions that should take place between doctor and patient. The consequences of permitting direct to consumer advertising are all too evident in the US system where doctors are under pressure to prescribe drugs that patients may have seen on television rather than according to clinical need, and where prescribing patterns can be based on the effects of skilful advertising rather than on appropriateness and cost. Most patients do not have the specialist knowledge required to differentiate between similar medications and are likely to be heavily influenced by advertising. More information on the BMA's views on this issue can be found in our two responses to recent EU consultations on the issue which are enclosed.

The BMA does not believe it is self-evident that all genetic tests, simply by being DNA tests, require additional protection or restriction. It is the implications of testing that raise concern and, in some cases, the implications may be no more serious than non-genetic tests that are freely available such as cholesterol testing. In making decisions about the need for regulation, or limits on advertising or service provision, the emphasis should be on the risk of harm rather than the type of testing. It is important with all tests that accurate information is provided and that those providing the service provide information about what the results mean for the individuals. With genetic testing this will include information about any implications for future insurance or employment applications. The Human Genetics Commission has done a considerable amount of work on this issue, including public consultation on the regulation of direct to the public genetic tests. The BMA is broadly supportive of the views and recommendations of the HGC. In addition, at its Annual Representative Meeting last month the BMA decided to lobby the Government for regulation of the marketing of direct to consumer screening tests (see response to question 14).

TELEMEDICINE

Question 9 Your experiences

Have you used information technology to access individual health care expertise at a distance?

If yes, which services did you use, what led you to do so, and how would you evaluate your experience? Would you recommend it to others?

If no, if you were faced with the choice of using such technology or undergoing the costs and/or inconvenience of travel over a substantial distance to access or provide those services on a face-to-face basis, what factors would affect your choice?

[3] British Medical Association. Boosting your brainpower: ethical aspects of cognitive enhancements. A discussion paper from the British Medical Association. London: BMA, 2007.

This question is not relevant to the BMA but some general points might be helpful.

One frequently used form of telemedicine is the telephone which forms a useful part of primary care assessment as nearly everyone has access to one and it is convenient to the patient and time-effective for the clinician. Most practices offer telephone consultations for discussing results, response to medication and deciding if symptoms need a face-to-face consultation. The problem with more technological methods is that they are less widely available, largely due to expense and the patient may have to travel some distance to access them. In order to be most effective there needs to be someone available to carry out an examination under instruction from a more senior but remote clinician. Some nurse led minor injury units, for example, use video links to main A&E departments and these can be useful in supporting the nurse operating at a distance. This technology is also very useful for accessing lab results and remote reporting such as x-rays and MRI scans.

The BMA's general view is that telemedicine has an important role alongside the traditional doctor-patient consultation. It has a number of advantages as one part of a flexible approach to healthcare that enables patients to receive the best care in the most appropriate, efficient and cost-effective way. It will never replace face-to-face consultations, nor should it, but it provides a useful tool for some patients within some areas of medicine. There are issues that need to be addressed such as the quality of images, confidentiality etc but these are not insurmountable. As mentioned in the general comments at the beginning, it is unclear how telemedicine fits into the general topic of this consultation.

Question 10 Who pays?

Should remote access to GP services be provided through telemedicine for those in remote and rural locations?

If yes, provided this results in higher costs: should it be the patient or the public health care provider who pays for the extra cost of providing services this way, or should costs be shared in some way?

If no, what are your reasons? Do you think some degree of unequal access to public health care is simply justified (for example, if individuals choose to live and work or retire in remote rural areas)? Or do you think that there are means other than telemedicine that are betters suited to achieving more equitable access to health care?

Those who are entitled to NHS treatment should receive it on the basis of need, free at the point of delivery irrespective of where they live. Telemedicine may have a role in some remote areas but this should be in addition to, rather than instead of, face-to-face consultations. Where telemedicine is the most effective way of delivering healthcare, and this incurs additional cost, this should be paid for by the health service.

BODY IMAGING AND DNA PROFILING

Question 11: Your experiences

Have you used the services of a body imaging or DNA profiling company?

If yes, what led you to do so and how would you rate the services of the company? How useful was the information you received? Please indicate which provider and which service package you used.

If no, if you were thinking about using such services, what information would you want to receive in advance and what kind of information would you find most useful to receive after the profiling?

This question is not relevant to the BMA. The BMA's Board of Science published a report on this topic in 2005 (*Population screening and genetic testing)* which may be of interest. This can be found at: http://www.bma.org.uk/health_promotion_ethics/genetics/Populationscreeninggenetictesting.jsp.

Question 12 Regulation

Do you think it is satisfactory for DNA profiling and body imaging services to have to pass stringent evaluations before they are provided in the NHS, but for them to be readily available on a commercial basis without having to go through such evaluations?

If yes, why do you believe more stringent evaluations are required in the public sector than in the private sector? If commercial DNA self-profiling products were to be developed in the future, enabling people to profile themselves (or others) whenever they want, do you think any legal, regulatory or other restrictions should be imposed beyond those applying to existing self-profiling products, such as pregnancy testing kits?

If no, do you think the NHS requirements should be less strict, or that more regulation should be imposed on private providers? What measures would you consider most suitable? For example: disclosure requirements such as labelling rules; voluntary codes of conduct or "kitemarking" arrangements; legal requirements to restrict market entry; restrictions or bans on advertising; tougher penalties for breaches of established rules; or stricter post-market monitoring and surveillance.

Although not explicitly stated in the document, we assume the consultation refers to the use of body imaging and DNA profiling by healthy individuals rather than those who are known to be at risk or have existing symptoms. Although it is suggested that there is no regulation at all in this area, all private health establishments will need to be regulated by the Care Quality Commission. Although it is too early to say how this will work out in practice, our understanding is that this should ensure that certain common quality standards are met. From the information so far provided it also appears that this will include ensuring that information provided about the service is accurate and does not mislead about what is likely to be achieved. There are also restrictions applied by the Advertising Standards Authority and general consumer-protection legislation. Those providing tests or services should provide accurate information about the supporting evidence-base; some people may still choose to avail themselves of unproven tests or procedures but this should be an informed choice rather than one made on the basis of misleading or erroneous information.

There may, however, be grounds for restricting the availability of some tests to require the involvement of health professionals. Any such decisions should be made on the basis of the implications of the test rather than the nature of the test itself. It may be acceptable for some genetic tests, which reveal carrier status among those with no family history for example, to be made available directly to the public but for predictive genetic tests, particularly those for serious and untreatable conditions such as Huntington's disease, to be restricted to testing within a healthcare setting (whether NHS or private). There is a precedent for this with HIV where in 1992 it was made an offence to sell HIV testing kits directly to the public. The growing use of the Internet complicates this since individuals who want to seek testing could get around such restrictions by using companies based in other countries. An important issue for the NHS, therefore, is public education so people understand the limitations of these sorts of tests and the important differences between relative and absolute risk.

The BMA believes that genetic testing with the involvement and support of health professionals should continue to be the norm for most patients but does not believe there is sufficient risk of harm to justify a general prohibition on the direct to the public testing. When there is a high risk of clear and serious harm, such as with predictive testing for very serious, incurable conditions, there are good arguments for limiting the availability of testing but, when the risk is lower, these arguments are not persuasive. The BMA believes the marketing of direct to consumer screening tests should be subject to regulation (see response to question 14).

One of the most important issues direct to consumer tests raise is consent. In relation to informed consent, the information people receive about these tests is from companies' websites, the principal purpose of which is to persuade potential customers to buy their kits, rather than to offer unbiased, objective information about the value or otherwise of predictive testing. This is in sharp contrast with the norm in the Regional Genetics Service of non-directive genetic counselling. Genetic counsellors talk through the possible benefits and disadvantages of being tested and ask the person to think about how they would feel about the result if it was positive, negative or inconclusive. Following

genetic counselling, an individual may decide that they would rather not be tested. In contrast, it may be much less likely that someone will decide not to go ahead with testing once they have purchased a testing kit, for which they will have paid in advance.

The second consent issue is that, where the sample is taken at home and posted to the testing company, there is no guarantee that the person whose DNA is sent for analysis is, in fact, the person who has purchased the test. This leads to the risk that parents may send in their children's saliva in order to obtain information about their risk of future ill health.

Question 13 Responsibility for harm

The results of DNA profiling and body imaging may lead people to seek appropriate treatment. But it may also lead to harmful actions, such as inappropriate self-medication, or people may become more fatalistic, believing that there is no point in altering their lifestyles. In the most extreme cases some people could become suicidal as a result of the predictive information they receive. Should providers ever be held responsible at law for such harms?

If yes, in what circumstances? Should providers of other services such as pregnancy tests also be held responsible for what distressed or misinformed individuals might possibly do with the information they obtained?

If no, how, if at all, do you think the interest of vulnerable groups should be safeguarded?

Existing principles of law will apply here and so the issue is whether those delivering information owe a duty of care to the people receiving it and, if they do, whether they have breached that duty by delivering information without taking reasonable care. Even if they are in breach of their duty of care, for a person to be liable in negligence their breach of duty must have caused the sort of harm which the defendant was under a duty to prevent. In this sort of scenario, the person's own actions in reacting to information would probably be said to have broken the chain of causation. In our view, only in the really unusual scenario that the person delivering information was under a duty to prevent the person reacting in a particular way could there plausibly be liability for how someone reacts to test results.

The BMA has not considered the question of whether there should be changes in terms of legal liability. In other areas, where people choose to make purchases or access services they must accept some responsibility for their own actions. In order to do this, however, they need to be given sufficient, accurate information about the product, service or test and the possible implications arising from it. We would hope that those providing services will not only provide accurate information but also encourage those using their services to keep their GP informed of any results obtained that have, or may in the future have, implications for their health.

Question 14 Quality of information

Some have criticised current commercially-available body imaging and DNA profiling services for giving information that is of limited quality and usefulness. Do you think more should be done to improve the quality and usefulness of body imaging and DNA profiling services?

If yes, who should pay? Should there be publicly funded investment or should private companies be left to develop better methods?

If no, is it sufficient to rely on the so-called "buyer beware principle" in such cases, by putting the onus on the purchaser to find out about the quality and associated risks of the product they are buying"?

This question is confusing. It is not clear whether it is referring to the quality and usefulness of the information (as implied in the first sentence of the question) or of the service itself (as suggested in the second sentence). As mentioned many times above, a key issue in direct to the public services is the quality, accuracy and format of the information provided – this is the responsibility of the company providing the service. This information should provide data about the evidence-base, discussion of

the possible outcomes, information about how to interpret the results and the implications of them, explain where additional support can be sought (including whether there are health professionals available within the company to provide information and support) and, ideally, should encourage people to keep their GPs informed of any results obtained.

The BMA has concerns about the way in which screening tests are marketed direct to the public and the quality of information provided. At its Annual Representative Meeting last month the BMA passed policy that:

> "notes the GMC code of fitness to practise governs the provision or publication of information about medical services, by registered medical practitioners to the public, preventing the manipulation of "ill-founded fears for their future health" and
>
> (i) recognises that there is no legislation in the UK preventing allied health professionals from promoting screening tests using direct marketing (mailings, door-to-door salespersons) to members of the public;
> (ii) notes that screening tests have risks as well as benefits that extend above and beyond false positive and false negatives; and
> (iii) calls on the BMA to lobby the government for legislation of the marketing of direct to consumer screening tests.

The BMA will be following this up to seek protection for those to whom such marketing is targeted.

Reference in the question to publicly funded investment is confusing. If this is referring to public investment in improving the technology then this will depend upon its usefulness to the NHS and whether funds are available for this purpose. If it refers to the cost of regulating the service and/or information provided by private companies then this is part of a bigger question about the need for regulation. If a decision is reached that regulation is necessary then this is usually funded by those who are subject to regulation (as with the Human Fertilisation and Embryology Authority and the Human Tissue Authority).

OTHER ISSUES

Question 15

Are there any other issues we should consider?

We would suggest limiting, rather than expanding, the number of areas covered in order to provide more focus to the work.

Some basic assumptions are made in the document that require further exploration. For example, we are not convinced that those who seek private medical services directly necessarily consider themselves to be "consumers" in the way suggested. It may be the case that the individuals' own perception of their status depends upon the service being sought: where purchasers of elective procedures such as cosmetic services consider themselves to be "consumers", but those seeking testing or treatment for a health problem consider themselves primarily as "patients". This is an issue that deserves further consideration.

British Medical Association
July 2009

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 principal 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[4].

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[5]. 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

[4] BMJ 2004;329:816, BMJ 2005;330:113, BMJ 2004;329:809-810

[5] 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

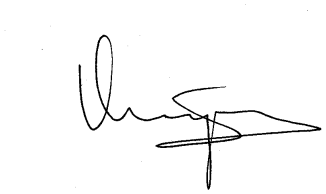
As stated above, the BMA supports the provision of information to patients and welcomes the opportunity to harmonise and regulate the quality of information available to European citizens. The BMA believes that this information should be provided by independent sources, in a transparent and high quality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



Dr Vivienne Nathanson
Director of Professional Activities

BMA response to the European Commission proposal for a directive on information to the general public on medicinal products subject to a medical prescription

The British Medical Association (BMA) is the UK's leading voluntary professional association and trade union for doctors with approximately 140,000 members which corresponds to around 68% of practising doctors in the UK.

The BMA has long engaged in the debate around the provision of information on prescription-only medicinal products and our previous paper on this issue can be viewed at: http://www.bma.org.uk/images/BMAresponsepatientinformation_tcm41-157697.pdf

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 important for the treatment process.

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 treats potent medicines as simply another consumer product and adversely influences the discussions that should take place between doctor and patient. The consequences of permitting direct to consumer advertising are all too evident in the US system where doctors are under pressure to prescribe drugs that patients may have seen on television rather than according to clinical need, and where prescribing patterns can be based on the effects of skilful advertising rather than on appropriateness and cost.

The BMA is pleased that the European Commission's proposal for a directive maintains the ban on advertising. We are concerned that definitions of 'advertising' may differ between member states which could result in the creation of loopholes to the ban. The BMA calls for a single definition of advertising to be included in the final directive in order to provide legal certainty for both pharmaceutical companies and patients. Without this, the distinction between 'information' and 'advertising' will be difficult to define and to police.

The BMA is grateful that many our previous concerns regarding the provision of information have been accepted by the European Commission. Article 100d of the draft directive is faithful to earlier BMA calls that all information must be objective, evidence-based, up to date, understandable, accessible, transparent and reliable. The BMA is also satisfied that the information provided shall be limited to a defined list of approved product characteristics and the contents of the package leaflet as defined in Article 100b. We remain concerned that there is a fundamental conflict of interest between the business interests of the pharmaceutical industry and its ability to become a primary provider of objective and unbiased information.

The BMA believes that health professionals should remain the primary source of health information particularly on treatments and medicines and that the primacy of the dialogue between healthcare professionals and patients must be protected from the potentially damaging impact of misinformation. We welcome the proposal in Article 100d that any information shall include a statement indicating that the information is not intended to replace the doctor-patient relationship. We are concerned that this may be open to abuse. The marketing holder may simply relegate this piece of information to the 'small print' where it will not be immediately visible to patients.

The BMA welcomes the European Commission's decision to prohibit the provision of information via television and radio. The BMA has voiced grave concerns on this over the past two years and is pleased that the Commission has taken action to protect patients from the confusing mix of information and advertising that would have resulted if information via these forms of media was permitted. The BMA further welcomes the proviso that information can only be presented in health-related printed publications rather than in the popular press. This stipulation should go some way to protecting patients from the 'push factor' of unsolicited information. We remain concerned that without a definition of advertising for the purposes of this directive, the distinction between information provision and advertising will be blurred.

The BMA calls for further clarification on Article 100g of the draft directive which relates to the monitoring of information. We are pleased that monitoring should be based on the control of information prior to its dissemination but question the exceptions to this given in the two sub-sections to part 1 of this article. The BMA calls for further clarification and warns that whilst the text of the information may have already been approved as part of the package leaflet, the images and graphics may not have been approved and may be designed in a way which could mislead patients.

The BMA believes that the current system of regulation and monitoring that exists in the UK is a model of good practice that can be exported to other member states. The BMA does not want new sets of rules to dilute the current high quality of information provision in the UK. On the EU level, whilst the BMA welcomes moves to harmonise information provision we caution that this should mean raising standards towards the best practice available and should not mean lowering them to the lowest common denominator.

In conclusion, the BMA is pleased that the draft directive appears to suggest sensible proposals compared to those contained in earlier consultation papers. The BMA is also pleased that dangerous suggestions such as the provision of information via television and radio have been scrapped. We remain concerned that the fundamental distinction between information and advertising has not been fully addressed and that the draft directive is not sufficiently robust to prevent abuse and to protect patients from the dangers of misinformation.

BMA
February 2009