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 (see Annexes 4 and 5) – 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?

This question does not distinguish products that require a medical prescription from those that may be purchased on the advice of a pharmacist from those that may be purchased without formal guidance (e.g. via supermarket or online). We are responding here assuming the third scenario is intended by the term "consumer good".
In principle we are supportive of this direction. There is a need to recognise the growing expertise of individuals in self-care, and avoid sustaining an over-patronising model of health care (which is also expensive). Experience of deregulation to date has largely been favourable. However, increased provision of goods and services needs to be matched with commensurate increase in protective mechanisms.
But, the choice of what medicinal products or devices to make directly available to the public needs to weigh up the likelihood that most people could make appropriate decisions to choose to use that product, could use it correctly, could recognise if a worsening or complication arises, and also that individuals are very unlikely to inappropriately choose to use the product. This set of factors inevitably requires judicious choice of the conditions and products to be made consumer items, and also that there is sufficient public access to education to inform appropriate choice and usage.
A further challenge with planning for such deregulation is the impact of advertising, which is discussed in response to Question 8.
A growth in the consumer goods market should also be considered alongside the promotion of standards based (interoperable) personal health records, to encourage the documentation of usage of consumer products in PHRs in ways that can subsequently be shared with the electronic health records of clinical teams should this prove useful as part of shared care or to investigate a problem.

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 raises 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?

We agree that they probably do raise different questions and should be subject to different regulation. Each set of information types have different risks associated with dissemination. The guidelines could offer an opportunity to analyse these risks and provide informed decisions about whether data subjects feels that this information should be shared or not in the first place, and data owners need to make informed decisions about what they are sharing. Some form of regulation needs to be in place so that information clients are very clear about what information they are receiving and it is not open to interpretation , thereby limiting the risks of misinterpretation. Furthermore, the risks/errors in genetic information need to be more carefully articulated – one of the real risks at the moment is that of over-confidence in genetic information (similar to the issues that arose in relation to fingerprinting technologies).

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 sometimes suggested that individuals should bear a greater fiscal responsibility for health issues arising from their own lifestyle, but this argument is usually aired in public fora without rigorous consideration. If such a policy were to be adopted universally even for existing health situations, almost every dimension of health care could be argued to have some lifestyle contribution, from diet to sports to occupation to stress to fashion choices. As we uncover more and more about the aetiology of illness, this web of causations is likely to increase and complicate. Will we start to penalise teetotallers for NOT drinking a few units of alcohol per week? Should a cyclist be congratulated for keeping fit and keeping the planet greener or be blamed when injured through an accident?
With these newer forms of information, as indicated in response to question 2, there is much less certainty about the predictive value of genetic findings. It would therefore be surprising if a case could be made for individuals having behaved improperly by not responding to them. These tests can reveal considerably more than conventional screening, and is it morally right to require everyone to discover such details about themselves. (note: we still permit couples not to be told the gender of their baby to be.)
The other implication of this topic is the suggestion that everyone should bear personal responsibility for the costs of their own healthcare, implied by the suggestion of taxpayers/policyholders in some way subsidising the costs of others. The purpose of pooling risk and costs is to protect against significant costs. It is unlikely that a moral argument can be made here to run counter to the basic principles behind the insurance industry.

In any case, it is probably best that individuals be fairly and appropriately advised so that they or their proxy can make informed decisions about what to do. It is unlikely that imposing expectations will *per se* instil a sense of responsibility, and any encouragement beyond professional and considered advice runs the risk of undermining that responsibility. Furthermore, any advice would need to be supported by public initiatives to educate/counsel people (particularly vulnerable groups using these services).

Question 4 Who pays?

Many DNA profiling and body imaging services (see Annexes 4 and 5) 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 services)?

This is part of a much wider debate on the relationship between private and publicly funded healthcare – ethically, it is not so different to the debate over top-up fees for specific cancer treatments.
This is also not a new situation: private health screening has often generated health concerns that are then brought to the attention of the patient's GP. If the health issue arising from newer test results is normally something that the NHS would address, it would be difficult to argue that the NHS should waive its responsibility on the basis of the route by which the health issue has been discovered. However, the NHS will need to determine how to handle potential discoveries that are not normally remedied via the NHS. This is also not a new scenario (e.g. infertility treatment), and guidelines may need to be drafted.

Question 5 Your experiences

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?

From what we have seen, there is potential in this approach, but it should be based on authoritatively collected information, and value lies in the fostering of patient self-responsibility, which is a much bigger issue than the mere provision of a recording system. Furthermore, the issues raised by personal health records in general, as exemplified by Google Health and Microsoft Health Vault, are more complex than can be addressed in this response. A more dedicated consultation on personal health records and the personal/professional boundary might be of value.

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 is currently not prohibited in the UK, see Annex 7)?
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?

Once advertising is condoned, it carries with it an ethical responsibility to offer more support to consumers than is probably practically realisable. Our response to this question should be considered alongside our response to question 1, in which we indicate a favourable view on the support of self care and the widening of the consumer products with careful choice and accompanied by suitable public education. Advertising tends to promote more expensive solutions over simpler and cheaper ones, and is driven by priorities other than effectiveness and value for money. Observation of US medicinal product advertising, which is more widespread, and of Internet pharmacy sites, reinforces that view. It is difficult to know if a responsible

code of practice can be found for such advertising that does not mislead individuals into favouring a promoted solution to a problem without presenting the alternatives.

Given that the evidence and certainty of the findings from new generation screening services is not yet strong, it would seem unwise to fully de-regulate the advertising or other promotion of such services.

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 better suited to achieving more equitable access to health care?
>
> **This question, despite a preamble indicating a broad definition of telemedicine, implies a narrow and out of date view. Telecare is a growing sector of health care, with near-patient monitoring and wearable devices enabling significant advances in the ways in which illnesses are managed. There is an assumption in the question that telemedicine is an additional cost burden of exclusive benefit to rural residents, as opposed to a novel part of the way in which care is delivered right across the healthcare sector. It is indeed hoped that at times telecare may enable patients to be discharged from hospital early because of remote monitoring, thereby saving money. Telemedicine has sometimes been used internationally to enable less experienced or less qualified staff in small town care settings to benefit from expertise in large city hospitals. This has at times enabled a national clinical service to be delivered more cheaply than providing senior expertise at all sites. It is certainly not the case that the benefit and business justification for telecare are limited to supporting rural communities.**
> **The question is actually worded more broadly than telemedicine, seeking a generic response on the acceptability of unequal access to health care. This might give rise to responses to this question that are not applicable to telemedicine.**

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.

It is advisable to have a regulatory and governance process in place for the use of such testing and access to derived resources. The private sector could be perceived with less credibility if it does not have the same stringency and assurance for validity and liability where sharing the test results or reusing them afterwards are concerned.
It is ethically unjustifiable to effectively use regulatory requirements to endorse different standards of care in the two sectors.
It is not unusual for the NHS to adopt a policy of NOT sanctioning the availability of high cost treatments that are new. NICE was indeed formed to help provide guidance on the appropriate use of high costs treatments, including the clinical indications that should qualify for NHS-funded treatment. Infertility and cancer are two such example areas. In these kinds of situations, there has often been a fudging of whether the grounds for withholding or restricting a treatment from the NHS are on efficacy or safety or national

affordability grounds. The successful and appropriate use of these novel screening techniques will not be helped by a similar fudging.
The obligations to demonstrate the safety and utility of novel treatments rests equally on private and state health systems, but the obligation to demonstrate value for money and cost-benefit is not equal for both health systems. It would be reasonable for the NHS to introduce a set of well defined and evidence based criteria that indicated priority use cases for these screening services. It would not be reasonable for the NHS to simply deny the potential value of these measures.

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?

This would depend on the nature of the relationship between the two parties – is it one where the provider could be deemed to have sufficient knowledge of the recipient to owe them a personal duty of care?
Very few investigative processes in medicine are without a risk of error. However, notwithstanding this, some procedures are known to give a probabilistic indication rather than a certainty. Screening for birth defects is one such example, and in such cases couples so need to make very critical and influential decisions on the basis of a statistical likelihood. The challenge for these new screening measures is that the degree of certainty of the findings is not yet well known. With birth defect screening couples are offered expert advice on the interpretation of the results and counselling if tough decisions need to be made.

It is not reasonable for providers of tests that have an inherent and unavoidable uncertainty to be held liable for the existence of that uncertainty, but an obligation and consequent liability would seem reasonable for the explanation, education and counselling offered to patients who have such tests, whether privately or state funded.

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 implies that more does need to be done to improve the quality of the information provided, In view of our answer to question 13, which places an emphasis not just on information but on providing patient specific explanation and counselling, the costs of these supportive services need to be considered as part of the total cost of providing that screening service.
However, if the NHS anticipates or starts to experience an increase in public concerns and clinical workload as a fall out from such screenings, even if privately performed, it might be in its business interests to invest in good quality educational materials about these tests even if it is not providing them itself. As an example of this, the NHS has invested in smoking advice and cessation support services even though it is not connected with the tobacco business sector. It also provides travel vaccination advice even though the private sector sustains the market for holidays.