The response reproduced below was submitted further to a consultation held by the Nuffield Council on Bioethics on its Report: *Pharmacogenetics- ethical issues*, during November 2002 – February 2003. The views expressed are solely those of the respondent(s) and not those of the Council.

The Hellenic National Bioethics Commission

Q1: What do you think will be the likely economic impact of pharmacogenetics on the development of new medicines?

In the field of pharmacogenetics, research and development (R&D) may demand today higher investment than conventional drug design. This increased investment in combination with the fact that the new medicines are designed to target a smaller patient population size will raise the individual prices of these drugs. Given that pharmacogenetically designed drugs getting approval are expected to be more efficient for patient treatment than conventional drugs, the overall economic impact on healthcare cost eventually is likely to diminish.

Q2: Do you think that further regulatory measures will be needed to encourage the development of clinically desirable but economically unprofitable medicines?

Yes. Regulatory measures should ensure that there is availability of appropriate drugs for all population groups, i.e. by means of public sector's contribution to R&D amortization so that the final price is kept to affordable levels.

Q3: In your view, should pharmacogenetic testing of participants in trials be a regulatory requirement for the development of medicines in the future?

Yes, in case the specific medicine is designed for a target group defined on a genetic basis and on condition the participant gives his informed consent.

Q4: Who should be responsible for providing a pharmacogenetic test? For individual therapy, should tests be available directly to patients over the counter or on the internet, or should they only be available through medical practitioners as part of a decision about the use of a prescribed medicine?

Only medical practitioners should be responsible for providing pharmacogenetic tests.

Q5: What will be the implications of pharmacogenetics for pharmaceutical companies and providers of healthcare regarding legal liability for adverse reactions?

The implications are not different than today. However, since in the foreseeable future the genetic test will only provide probabilistic information it is advisable that healthcare providers stress the probabilistic nature of the test.

Q6: Should medicines which have been developed for administration in conjunction with a pharmacogenetic test be distributed to countries in which testing facilities are not available?

In principle yes, because it is the responsibility of the receiving country to decide whether a new drug will be distributed in its population and not of the sender.

Q7: How should predictions of efficacy and safety as well as cost, be integrated in deciding whether to provide a particular treatment to patients in (a) public healthcare system, and (b) a private healthcare system?

This is general question not particularly linked to pharamcogenetics.
In principle, efficacy and safety are the important criteria for administrating a treatment to a patient, whether this occurs in a public or private healthcare system.
If the expectation that new drugs designed using pharmacogenetics will have (from the beginning or eventually) a lower healthcare cost, then integrating cost considerations in decision-making are not founded. However if this expectation turns out to be false and as far as the public healthcare system is concerned, the answer is bound by the extent to which health is prioritized in respect to other domains of public support.

Q8: Do you think the application of pharmacogenetics might exacerbate inequalities in the provision of healthcare? Is it likely to challenge the principle of solidarity that lies at the basis of the provision of national healthcare in the UK? Will the benefits of pharmacogenetics only be affordable to the wealthy?

It may or may not exacerbate inequalities in the provision of healthcare. This is will depend on Q2 and Q7.

Q9: In your view, is the storage of genetic information for the purpose of pharmacogenetic analysis categorically distinct from storage of other kinds of genetic information, for example information about susceptibility to disease?

No.

Q10: What level of anonymity should be accorded to genetic information stored as part of research in pharmacogenetics?

Certainly they cannot be readily identifiable. Coded (or double coded) should be enough or anonymous depending on the kind of research.

Q11: What kinds of consent should be required for the collection of samples for research in pharmacogenetics? Should pharmaceutical companies, which collect samples in the course of research in pharmacogenetics, be able to use such samples for any purpose, or should consent of the donor be restricted to allow usage only for specific kinds of research?

Given that pharmacogenetics research requires access both to biological samples and medical files of the participants, different types of consent might be required according to the level of protection of the participant's anonymity. In case of non-anonymous data, there is a requirement for specific informed consent and further research should seek for renewal of the participant's specific informed consent. For anonymous data, any pharmacogenetics research should be possible.

Q12: Do you think that researchers should provide individual feedback about genetic information obtained from participants in research in pharmacogenetics?

Researchers should provide individual feedback only when of clinical relevance.

Q13: What, in your view, would be appropriate methods of regulating scope, storage and access with respect to pharmacogenetic information used in clinical practice?

Appropriate methods of regulating scope, storage and access of pharmacogenetic information could be, either publications of binding guidelines issued by the relevant ministry or by law. In any case, this can only concern non-anonymous information collected for patient treatment and should only be accessed for further clinical use given the patient's specific informed consent.

Q14: Do you think that the ethical and legal issues raised by the use of pharmacogenetic tests in primary care differ from those raised by other forms of genetic testing? What about non-genetic tests, such as tests for cholesterol?

No. They do not differ fundamentally within the context of medical care.

Q15: What might be the psychological implications for individuals of pharmacogenetic tests? Are such tests likely to reveal information that is of relevance outside the context of testing for response to medicines?

Possibly negative psychological implications will occur in case the genetic test reveals that the individual tested does not fall within the category of those who responded to drug (during R&D). Alternatively positive psychological implications will occur if the tests support expectation for efficient treatment.
It might be, in those cases where polymorphisms related to drug response are found to be linked in the future, to other medical or non-medical characters. But this is true for all genetic tests.

Q16: What implications do you think pharmacogenetic tests might have for family members?

The implications of pharmacogenetic tests for family members are similar, but milder, to the above mentioned.

Q17: In your view, are controversies likely to arise about who ultimately decides which treatment is prescribed in light of a pharmacogenetic test?

It may arise when there is a clear indication for a particular drug based on pharmacogenetic testing but patient request a conventional drug less effective. However, this can also arise whenever more than one possible theurapeutic schemes exist.

Q18: Should patients be able to refuse a genetic test to determine response to medicines but still expect to receive a prescription?

Yes, according to the principle of autonomy. If the patient refuses genetic testing, it is the physician that decides which treatment is likely to be more effective and thus he will prescribe the medicine accordingly.

Q19: Do you think that the providers of health insurance should have access to pharmacogenetic information? What about other parts of the insurance industry, for example life insurance?

In principal no. Only the treating physician might have access to such information confidentially.
Disclosure of genetic information to public social security funds is unacceptable even with the consent of the insured or prospective insured. This solution is justified by the nature of social security as public good which should be made available to all without discrimination. This holds not only for genetic but all medical information.
As far as private insurance is concerned, disclosure of genetic information remains unacceptable when the insured or prospective insured is not covered by public social security. This solution is justified by the unequal position of the insured vis-à-vis the insurer.
However, when private insurance is complementary to social security, disclosure of genetic information is allowed provided the insured or prospective insured consents in accordance with the principle of freedom of contract. However no additional pharmacogenetic tests should be required by the insurance as a condition for granting the insurance.

Q20: Do you think that pharmacogenetics will increase the likelihood of the grouping of patients according to racial or ethnic groups for medical purposes? If so, what might be the ethical and social implications of such an outcome?

There are pharmacogenetic polymorphisms known to have different frequencies in different racial or ethnic groups but differences are not substantial for most of them. Although it cannot be excluded that some new pharmacogenetic polymorphisms will exhibit more pronounced racial or ethnic patterns it is unlikely that grouping of patients on such grounds will either be of substantial medical relevance or attract discriminatory pharmaceutical investment. However, regulations excluding discriminations on racial or ethnic grounds in relation to health should be adopted beforehand.

The response reproduced above was submitted further to a consultation held by the Nuffield Council on Bioethics on its Report: Pharmacogenetics- ethical issues, during November 2002 – February 2003. The views expressed are solely those of the respondent(s) and not those of the Council.