Mrs Valerie Inglis, Forth Valley Research Ethics Committee, UK

General

There are more major ethical problems at the Research and Development stage (p7) than at the Treatment stage (p8). Pharmaceutical companies are less likely to spend the sums needed to develop medicine for less common conditions OR for the groups or people who can't afford to pay for them. Racial or ethnic sub-groups are by definition genetically defined so the emphasis will be even more on drugs for the big diseases in the affluent West. Makes commercial sense. With respect to treatments using drugs already developed and available the outlook for the application of pharmacogenetics is much more positive.

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

- The main beneficiaries will be the rich, developed countries. Within these again the affluent may be further advantaged but in a country like the UK this is not likely to be a major factor due to the provision of the NHS.

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

- Yes, but pharmaceutical companies plan for global markets so that regulation within one country to influence their development strategy is important but probably would not be very effective.

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

- Yes, absolutely.

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?

- Through practitioners.

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

- In tests participants will be protected through ethical requirements in place for drug testing. When using pharmacogenetics to guide on prescription the aim is to encounter fewer adverse reactions so adequate information and a signed disclaimer is enough. The problem is that the test will take time and money and this may delay start of treatment – antibiotics have often been prescribed without sensitivity test results. There could be a liability for delay.

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?

- Yes. That is where we are at present. However very clear warnings should be given about sharing any information gained through pharmcogenetic trials that suggests reduced expectation of success, or dose level needed or increased risk of adverse reaction. Emphasise the warnings.

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) a public healthcare system, and (b) a private healthcare system?

- a) There will need to be set parameters of efficacy at which the clinician may choose to use the drug. Within these limits he/she must use clinical judgement.
- b) In the private healthcare system, the informed patient should decide the parameters they are prepared to accept.

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 or available to the wealthy?

- Everyone will be benefited because with the additional information they get more tailored treatment. In the private healthcare system a patient can 'try' a medicine that statistically is likely to be of little use. It might work. But the probability is that the outcome will fit the data set already generated so overall the difference is not going to be great. The problem of inequality lies much further back i.e. in getting medicine developed at all.

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?

- Yes, it is distinct and should be subject to agreed terms of storage. However there needs to be debate about what should happen to other information derived from the data; there might be a case for allowing some data to be transferred to another category e.g. information showing propensity to a disease and held there so that it might later be useful to the donor.

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

- I don't have a definition of 'coded' or 'double coded' but the latter sounds about right.

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?

- If companies need to get separate clearance for use for each separate usage it will multiply the paperwork. If the issues in Q9 and Q10 are dealt with adequately there should be no further problem here – let them use the material.

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

- No. This places a huge load on the research team; it would need to be done with guidance and counselling; with studies incomplete it could be difficult to interpret and misguiding information could be given.

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

- In clinical practice access should be limited to the specific purpose for which it was obtained and then the record destroyed. If needed later a second application can be made to the data holding facility.

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?

- When linked to the name of an individual, the information must be confidential. I am not sure about legal position on other genetic testing.

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?

- Worrying information could be uncovered and this could have psychological implications. However this progress is inevitable and we are going to have to learn how to accept this kind of information in a positive way. Can't hide significant medical information.

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

- Don't know.

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

- Don't know.

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

- Yes. Absolutely, anyway this method has not yet been evaluated. How do we KNOW that it really does improve treatments.

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?

- No. As well as 'no' the reply to Q17 also holds here.

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?

- This is inevitable and was also the problem highlighted about how pharmaceutical companies will decide what drugs to develop.