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Professor Roberto Llanos-Zuloaga, President, Peruvian Society of Bioethics, Peru

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

- The pharmaceutical industry will be unlikely to develop medicines for very small groups of patients.

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

- The research and development of such medicines must be promoted by providing such incentives through specific regulation

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

- If pharmacogenetic tests are technically feasible, it would need to be considered to whom the obligation should fall to provide the test both during research and in clinical practice.

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?

-As regards clinical practice, GPS, pharmacists and patients themselves will all be implicated, as tests could become available both through healthcare professionals and over the counter or on the internet.

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

To date, no regulatory authority has specifically addressed the management of pharmacogenetic tests in research, development, and licensing of medicines.

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?

Subsequent decisions about making medicines available to providers of healthcare and finally to patients are the remit of other bodies.

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 in (b) a private healthcare system

At present it is unclear how public and private providers of healthcare will react to the expectations of patients.

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?

Pharmacogenetics could help to reduce costs in the provision of medicines by enabling more efficient treatment, allowing prescription only for those patients who are likely to be responsive to a particular treatment. Alternatively it may be that pharmacogenetics increases costs because of the additional administrative burden.

Q9:
In your view, is the storage of genetic information for the purpose of pharmacogenetic analysis categorically distinct from storage of other kinds

The EMEA has recently presented a system for the classification of samples used in pharmacogenetic research.

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

It is impossible to link the sample back to an individual, which would provide complete protection of the privacy of a trial participant.

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?

Consent is necessary in order to replicate or dispute findings that other researchers might present at a later date.

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Q 12:
Do you think that researchers should provide individual feedback about genetic information obtained from participants in research in pharmacogenetics?

As in France, medical information, including genetic information, require that participants in research should receive individual feedback.

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

Genetic samples taken specifically for a pharmacogenetic tests must be subsequently destroyed.

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?

In providers of healthcare or primary care, patients are able to refuse a pharmacogenetic test, even if it is availale and relevant to their treatment. Doctors must be willing to prescribe medicines for which tests exists if the patient has not been tested.

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?

As a consequence of a pharmacogenetic tests, individuals may find it more difficult to find affordable health insurance. These labels may have a negative effect on an individual´ s perception of themselves.

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

Information about the the likelihood of adverse events to a medicine may be important to other family members, particularly if it transpires that one genetic variant has an effect on more than one medicine.

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

All treatments have the basis of a medical practitioner´ s decision s to wether a patient qualifies for a particular treatment.

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

Non been tested patients are able to refuse a pharmacogenetic test, and doctors are willing to prescribe medicines for them.

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?

As a consequence of access of a pharmacogenetic test, individuals may have to pay higher premiums because of their potentially poor response to treatment, regardless of wether or not they develop the disease for which the treatment would be used.

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?

It is very difficult to develop effective medicines for particular racial or ethnic groups.