RIGHTS OF THE PATIENT AND PHARMACOGENETIC BASED MEDICATION, A NEW CHALLENGE FOR HEALTH LAW

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Pharmacogenetic analysis is still in its infancy. This allows for a timely assessment of its possible impact on patients rights and other health law issues. Relevant questions include the following: to what extent and how does pharmacogenetic analysis affect the patient's right to know and not to know? What are the consequences for the doctor-patient relationship and the professional autonomy? What is the impact on the right to equal access to health care (distributive justice) and what are the consequences for the patient of third party interests?

Pharmacogenetic analysis is an important instrument for improving safety, quality and efficacy of medicines, as well as for their cost-effectiveness. Pharmacogenetic analysis is likely to become mandatory when developing medicines, as part of the license regulation and prior to prescription. If pharmacogenetic analysis is not applied where it should have been, claims may arise when patients experience serious adverse events.

With pharmacogenetic analysis the patient can be spared a "trial and error" approach, adverse-reactions can be minimised, dosages can be adapted to the personal condition, and in case specific genes in the diseased tissue play a determinant role, it allows for identification of effective targets for medicines.

On the other hand, the analysis may provide the patient with predictive information (response to a particular medicament and/or on susceptibility for developing a disease). The information may be of interest to relatives and can be used by insurance companies to categorise individuals (difficult to treat, expensive etc). The smaller the group of patients likely to respond positively to a medicament, the lesser the chance a suitable medicament will be developed for this group.

In relation to the international scale of the research and development of new medicines, a pertinent question is through what kind of arrangements the rights of participants in the research (informed consent, privacy) can be respected and safeguarded taking into account the national (and regional) variations in implementation of common shared human rights principles.