MEDICINES MADE TO MEASURE - LOPES DÍAS & ASSOCIADOS

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The emergence of new areas of medical research such as pharmacogenomics present not only new regulatory and clinical trial issues, but also impact significantly on data protection regulation, says Maria de Lourdes Lopes Dias of noted Lisbon IP and life sciences firm Lopes Dias & Associados.

Los farmacogénicos presentan una nueva forma de investigar y desarrollar medicamentos, que considera no solo el impacto de los mismos en el ADN de las personas, afirma Maria de Lourdes Lopes Dias, socia de Lopes Días & Associados en Lisboa, sino que también ofrece nuevos aspectos jurídicos en temas vinculados a pruebas clínicas, y de regulación y protección de datos.
Pharmacogenomics is a process that enables drug manufacturers to very specifically target diseases based on patients own genetic make-up. 'But while it presents a potentially very powerful form of fighting diseases, it nonetheless raises many new legal issues.'

Pharmacogenomics studies focus on the impact of drugs at a DNA level (hence the name linked to genome), and require researchers to take blood and tissue samples from clinical trial patients before

and after the application of a drug, she explains. 'Such a process encompasses clinical trial regulation, informed consent and data protection rules, but ultimately extends beyond all of these,' she says.

In Portugal, such research would, for example, require the consent of the regulatory body that oversees clinical trials – INFARMED – the applicable ethics committees of the hospitals conducting the trials, and the regulatory body that advises on the suitability of tissue for transplants – EVA.

In addition the collection of any data would be subject to privacy and data protection regulation, and could only be exported to a country that offers comparable or greater regulation than in Portugal, explains Lopes Dias. 'Portugal's data protection rules may be considered by some to be over protective, but the fact is that a matter of this importance needs to be dealt with very carefully by the proper authorities. In any event any information collected would remain the property of patients involved in a trial who would be entitled to have access to the results of the study.'

Portugal's clinical trial regulation was enacted in 2004, while the regulation covering the use of blood samples came into force in 2007. Also important, is that any samples removed must be fully traceable.

Pharmacogenomics may represent the future of medicinal research but anyone involved needs to fully understand not only the medical rationale but also the legal and regulatory issues it encompasses, she says.