

# Taking the medicine

Portugal's new Medicine Act has come into effect at a time of good health for Portugal's life sciences sector, says António de Magalhães Cardoso, senior partner at Lisbon's Vieira de Almeida. But local developments, he says, are to a large extent now, a reflection of the wider international scene.

With almost three decade's experience in corporate, regulatory and patent issues Cardoso is well placed to comment. He is currently engaged in a number of enforcement and validity cases dealing with major pharmaceutical products in Portugal. Vieira de Almeida is however, firmly on the side of the innovative manufacturers and counts among its clients a number of the leading international drug manufacturers, as well as the association of the Portuguese Pharmaceutical Industry Association.

## Confidence

"The most relevant industry developments, impacting on both our IP and life sciences practices, is probably the boosting of the generic drug market, together with a significant slowdown in the new medicines pipeline," he says, "despite significant levels of scientific progress and increasing amounts of money being spent on research activities by the innovative manufacturers."

An important milestone for the generics industry in the European pharmaceuticals market, he says, has been the approval by the European Union's European Medicine Agency's (EMA) Committee of Medicinal Products for Human Use, of the first generic biological product, early this year.

An estimated 30% of all new drugs on the market have their origins in biotechnology, with estimates suggesting that they will account for 50% of all new products by 2010. Generic products currently account for around 12% of the total \$550bn healthcare market. Consequently says Cardoso there are always strong defences launched by innovative manufacturers in an attempt to prevent generic products infringing on their key markets.

"The clash between the research based pharmaceutical industry and generic companies has substantially increased and IP is the front line of that battle. Indeed,

intellectual property rights (IPR) are always present in the debate on generic drug production and trade."

With generic products also now accounting for the majority of prescription medicines across the EU, a broader spectrum of players, he says, are arguing in favour of loosening intellectual property rights for the sake of both a cheaper access of patients to medicines and to relieve the burden on public expenditure.

"In line with such a trend, health authorities tend to pay little attention to any

**"The clash between the research based pharmaceutical industry and generic companies has substantially increased and IP is the front line of that battle."** António de Magalhães Cardoso, Vieira de Almeida

impediment to the granting of generic drugs marketing authorisations that may derive from IPR. The Portuguese courts are no different, they often lean towards invalidating or holding unenforceable nearly every pharmaceutical patent that comes under their scrutiny."

## Challenging

A number of the firm's clients, he says, have been heavily involved in negotiating pricing structures relating to the government's reimbursement programme, a key driver behind the new Medicines Act, which was introduced earlier in the year.

"The new statute is the most important regulatory and legislative initiative in the Portuguese life sciences legal environment. It essentially modernises existing regimes relating to the manufacture, quality control, safety and efficacy of medicines, and transposes a number of European Directives into domestic law."

Among the key changes, he says, is the elimination from the legal definition of generic medicines a requirement for any existing IPRs over the drug to have elapsed. "This goes against guidance previously issued to administrators on the importance of respecting third party IPRs."

For such clients, he says, the current atmosphere in Portugal is highly challenging.



La nueva ley del medicamento en Portugal, se ha aplicado en un momento de esplendor para el sector farmacéutico en Portugal, afirma António de Magalhães Cardoso, socio de Vieira de Almeida. En una entrevista, el mismo reflexiona sobre la evolución del sector tras tres décadas de experiencia y su involucración en una gran variedad de asuntos de gran envergadura en Portugal. El mismo indica que los cambios experimentados a nivel nacional son entre otras cosas un reflejo de los cambios que están acaeciendo a nivel internacional.