

# LIFE SCIENCES RISING TO THE REGULATORY CHALLENGE - SÉRVULO & ASSOCIADOS

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**A rise in regulatory pressure by the Portuguese medicine regulator, INFARMED, is prompting an increased questioning of its decisions.**

El aumento de la presión regulatoria de los medicamentos por la autoridad portuguesa, INFARMED, está provocando que se cuestionen sus decisiones por parte de las empresas de 'life sciences' dice Miguel Gorjão-Henriques de Sérvulo.

'We are not seeing a stricter position being taken to the market approval of medicinal products, but what we are seeing is a tougher stance being taken in relation to issues such as advertising and pricing, in which the regulations are being applied in an increasingly strict manner,' says Miguel

Gorjão-Henriques, partner at Sérvulo & Associados.

Life sciences companies have regularly challenged market approval, patent or tax decisions, but the emerging appetite to challenge these more subtle types of regulatory decision is a new development in Portugal, he says.

'Companies are now being much more proactive in questioning rulings that they perceive to be unfair or made improperly. The result is that the administrative authority in Portugal is now facing a kind of market pressure that they are not entirely comfortable with.'

The regulators are being made to stand up and account for their decision-making, says Gorjão-Henriques, who currently has twelve outstanding requests for information pending with INFARMED.

'The administration does not know how to deal with the issue. In the past they have made rulings without giving explanatory grounds and faced no repercussions, now the market pressure is such that companies are no longer willing to accept such an opaque decision-making process.'

Gorjão-Henriques believes however, that such developments may ultimately benefit the Portuguese life sciences sector and improve its competitiveness. Recent months have seen some companies question their commitment to the Portuguese market, he says, as a result of reduced sales, increasing price pressure from central government, growing regulatory barriers and the potential for greater returns from other markets.

'There remains a long way to go, but the hope is that increased pressure on the decision-making administrative bodies to produce more considered rulings and a willingness to debate their findings will help improve the international perception of the market more generally, which will benefit consumers, companies and Portugal.'