THE IMPORTANCE OF DEFINITIONS IN THE PORTUGUESE LIFE SCIENCES SECTOR - VIEIRA DE ALMEIDA

Posted on 30/10/2009

Category: Uncategorized

Generic medicines are playing an increasingly important and prominent role in Portugal albeit the innovative pharmaceutical industry is responding

Los medicamentos genéricos está jugando un papel muy importante y destacado en Portugal, no obstante la industria está respondiendo, comenta Paulo Pinheiro, Responsable del í rea de Público y Salud en la firma de Lisboa Vieira de Almeida. E pesar de todos los medicamentos genéricos representan el 15% del total vendido en Portugal.
Changes to the definition of pharmaceutical products following the introduction of Portugal's Medicines Code, has continued to raise issues for manufacturers, distributors and suppliers as the

government increasingly embraces the sector, says Paulo Pinheiro, the Head of Public and Health Law at Vieira de Almeida & Associados in Lisbon.

The Portuguese legal framework applicable to both 'innovative' and 'generic' pharmaceutical products is defined by the Medicines Code (approved by Decree-Law 176/2006, of 30th August 2006) which transposed the European Directive on Medicinal Products for Human Use (2001/83/EC).

'The Directive dealt with the disparities between certain national provisions, in particular those relating to medicinal products, which directly affected the functioning of the EU internal market. The Portuguese Code has closely followed the regime provided for by the Directive, particularly concerning the market definition of specific types of drugs,' he says.

Generic versions of drugs are virtually exact copies of well-known brand products, and usually marketed at a significant discount to the price of their better known equivalent. A generic product is broadly defined as one with the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference brand product, and whose bioequivalence has been demonstrated by appropriate studies, explains Pinheiro.

As is common elsewhere, prescription-only medicines are exclusively sold in pharmacies, while over-the-counter (OTC) medicines can be sold outside pharmacies, under the supervision of pharmacists or pharmaceutical technicians – with generics increasingly fighting for market share at both levels. Significant in this respect, he notes, is that the public prices of proprietary (innovative) medicines are initially subject to maximum prices restrictions, and that, as a rule, the public prices for generic medicinal products must be at least 35% lower than the reference product.

'The reference product – the innovator – is that which has been authorized on the basis of a full dossier presented to the relevant regulatory authority, infirmed in Portugal.

Generics may be authorised under an abridged procedure following the lapse of the innovator's data exclusivity rights – typically eight years as from the date of the relevant marketing authorization – although marketing is only possible after 10 years.'

The introduction of the revised Medicines Code therefore significantly reduced the timeframe within which 'innovative'manufacturers could have exclusivity around their product compounds, he explains.

'The notion of a 'generic' product however changed with the approval of the Code. Prior to this, and further to these other requirements, the classification of a product as a generic required the lapse of the industrial property rights of the innovator – which lasts for 20 years from the date of initial application.'

Such developments are important because of the growing importance that generics are playing in the domestic market, say Pinheiro. The generics market has been gradually and steadily increasing, and in these current times of economic uncertainty, and falling tax revenues, generics are increasingly attractive to governments, national health services and health service suppliers.

The total value of medicinal sales has risen between 2%-4% in recent years, to €3.3bn in 2008. In 2004 generic products accounted for only around 5% of total Portuguese market sales, by August of this year their market share had risen to slightly over 15 per cent – equivalent to around €400m.

'The Portuguese Government has been very active in promoting the generics for the last years, both through legislative measures, for example, aimed at expediting price and reimbursement approval procedures, reference price system and through campaigns, for example, in the media.'

The most recent Government measure has seen the free dispensing of generics to retired people and those on low incomes, he explains. This has now been challenged by the Apifarma – the

Portuguese pharmaceutical association – on the basis of discrimination, on which Vieira de Almeida is advising.