PHARMA MARKET UNDER (R)EVOLUTION

Over the past few months, the Portuguese pharmaceutical sector has been experiencing significant and revolutionary changes. These changes are essentially driven by the Government's need to reduce public expenditure in order to comply with the European Growth and Stability Pact. To this effect the Government has passed various legislative and administrative acts aimed at decreasing the current level of expense incurred by the State with medicines within the Health National Service. As a matter of fact such expenses have, over time, become increasingly high and it is therefore only natural that some form of rationalisation is now introduced.

To start with, a blind cut in prices of 6% on all reimbursed products took place on September 15, 2005.

However, the most impacting measures relate to pricing. Currently, the price system for products subject to medical prescription is very simple: the price of a medicine to be introduced in the market for the first time shall be equal to the lowest price in force in the country within a basket of three – Spain, Italy and France – where such price is the lowest. Thereafter, the price of the medicine will never take into consideration the evolution of the prices in force in those countries, which in most cases have suffered significant reductions throughout the times. The Government intends now to proceed with an annual adjustment of the prices by reference to said basket.

Besides the above annual adjustment, another measure has been announced, even more controversial and debatable from an European law point of view: the initial prices of medicines shall be 3% lower than those in force in the country (within the basket) where such prices are the lowest for the relevant medicine.

Another major change brought in the package respects the medicines not subject to medical prescription which may now be sold outside the pharmacies, as was made public by the Prime Minister himself. This measure was designed to decrease the prices of such medicines by eliminating the existing price control mechanism.

This has led the very strong lobbying National Association of Pharmacies (ANF) to take action intended for getting round this potentially significant loss of business, namely by acquiring vertical control of one of the major wholesalers operating in Portugal. This of course raises important competition issues and puts the market under pressure.

On the other hand, the possibility of purchasing medicines in the mass market has also re-launched the question of the ownership of the pharmacies (currently limited to pharmacists). The Portuguese Government is in the process of assessing ways of removing such constraint. In any case, this limitation on ownership has already been subject to the analysis of the Portuguese Constitutional Court who has passed judgement on the matter considering that the same does not violate the Constitution.

Last but not least, the fact that generics have, to such a great extent, been so much boosted by the latest Governments is now causing serious issues insofar as IP rights are concerned and we are witnessing increasing litigation for the protection of such rights by multinationals.

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