



## Andalusia anticipates the development of the selected price system for medicinal products and medical devices

### *Decree-Law 3/2011, of 13 of December, approving urgent measures on pharmaceutical provision of the Public Healthcare System of Andalusia*

On 16 December the Government of the Andalusia region published Decree-Law 3/2011. With this instrument the regional government aims at giving an impulse to a new reduction in the public expenditure on pharmaceutical products in Andalusia, on the basis of the new rules on prescription by active ingredient.

#### Main novelties

With this regulation the Andalusian government aims at introducing a system of selected prices for the medicinal products and medical devices that are dispensed in pharmacy offices in its territory with an official prescription of the National Health System, anticipating thus the development of such system that was foreseen in Royal Decree-Law 9/2011.

With this purpose, the Andalusian Health System shall carry out public tender calls in which the holders of those medicinal products and medical devices having a price equal to or lower than the lowest price established by the Ministry of Health may participate.

Among the submitted proposals those that represent the largest saving for the public treasury shall be selected, and the holder of the product shall be obliged to guarantee its supply, as well as to adapt its price to the successive lowest prices that may be approved subsequently, while maintaining the economic improvement on the new price. The duration of the agreements shall not exceed two years, and they may be resolved in case of a shortage of supply or in case that a new lowest price is

approved and the winner of the tender does not apply the economic improvement on the new price.

#### What about Law 29/2006?

The Andalusian regulation raises from the outset serious questions with regard to its compatibility with the regulation on the state level. In the first place, the selection system foreseen in the new Decree-Law may lead to the de facto exclusion of the products that have not been selected from public funding in Andalusia, which is not compatible with the idea that the minimum content of the pharmaceutical provision of the National Health System can only be set by the central administration. In short, the system elaborated by the Andalusian government neutralizes the efforts that had been channeled in this area through Royal Decree-Law 9/2011. On the other hand, Law 29/2006 itself establishes clearly that applying the selected prices system to a certain group of medicinal products shall only be carried out if such group has been excluded from the reference prices system, principle that would not be respected when applying the Andalusian regulation.

All of these issues make that the compatibility of this new regulation with our legal order be questionable, and we may expect some conflict as regards its application.