



## Substitution of medicinal products and individual rights of patients

*Judgment of the Court of Justice of the Basque Country of 3 February 2015 on the substitution of a branded medicinal product by a generic medicinal product*

### Background

This case began when a doctor treating a patient with Parkinson came to the conclusion that, in this specific case, the generic medicinal product which the patient was getting from the pharmacy did not have the same effect as the branded product which the doctor had prescribed. The substitution had been carried out by the pharmacist in a correct legal manner, because the branded product had a price higher than the generic. However, given the circumstances, the doctor encouraged the patient to buy the branded product, which would not be reimbursed, and to file a claim for reimbursement later on.

### The Law and individual rights

The Court that analysed this case ruled in favour of the patient, basing the decision on the need to protect his individual rights. According to the Court, what is crucial to resolve this case is not that the pharmacy was obliged to dispatch the generic product due to its lower price; but the fact that the patient had the right to protect his health and to obtain the branded product prescribed by the Neurology Service that was treating him if, in his case, the result obtained with the branded product were better than those obtained with the generic.

According to the Court the protection of the individual right of the patient is contemplated by Article 85 of Law 29/2006 on prescription, dispensation and substitution; because according to this article the principle that must prevail is that the prescription must be made in the most appropriate manner for the benefit of patients.

The Court also recalls that the same law provides that the sustainability of the system must be protected and it envisages that, because of this, the prescription and dispensation of the branded product is possible only if its price is not higher than the one of the generic one. However, according to the judgement, this rule has to be disregarded in the case of non substitutable products, and in order to determine whether a medicinal product is substitutable or not, it is possible and even necessary to take into account the individual situation of each patient. If the condition of a patient treated with a branded product aggravates when he starts being treated with the generic version, the Court says, these products must be considered as non-substitutable at least in the case of the specific patient.

### Selection and Substitution of biological products

The ideas expressed in this judgment contribute to the debate on the situation of patients treated with biological medicinal products. For these products, where prescribing by brand name is compulsory, and where identification of the brand and of the batch of the product administered to the patient is required for pharmacovigilance purposes, substitution without the consent of the patient and the prescribing doctor is not only illegal but it also infringes the individual rights of patients recognized in the Constitution. This applies to any type of selecting measure that implies generalizing substitution or that makes the prescribers treat the new patients with a biologic medicinal product to the detriment of another. The doctor's criterion, and the patient's right to be informed and to be able to choose from the available alternatives must prevail in all cases, and especially in this one.