



## A supplier may select his clients on the basis of objective, transparent and non discriminatory criteria

*Resolutions of the CNC of 14 November 2011 (Call forwarding) and of 1 December 2011 (Google); Judgment of the High Court of Justice of Madrid of 18 October 2011*

### Resolutions of the CNC

The Spanish Competition Authority (CNC, for its Spanish acronym) has recently issued two resolutions (“Call forwarding” and “Google”) arising from customer complaints who considered that they had suffered unjustified refusals of service provision and discriminatory treatment, which implied an abuse of the dominant position of the companies against which the claims were brought (Vodafone and Google, respectively).

In said resolutions, the CNC considers that the fact that a company holds a dominant position in a relevant market does not imply that such company is obliged to provide services to all the clients that request it, although it does generate a special responsibility in order to avoid falling into abusive practices. In this sense, the CNC points out that companies holding a dominant position must have the freedom and commercial autonomy to select their clients and to adapt their tariffs to the different realities existing in the market, as long as they base their decisions on objective, transparent and non discriminatory criteria.

Since it has not been proven that the companies against which the claims were brought offered any unjustified discriminatory treatment, the CNC concludes in both cases that there is no evidence of infringement of the rules on competition and it decides not to initiate any disciplinary proceedings, and no further action will be taken.

### It also applies to the pharmaceutical sector

In the pharmaceutical sector, a recent Judgment of the High Court of Justice of Madrid (TSJM) also ruled in favor of the freedom of enterprise, and rejected the appeal lodged by a wholesaler (Europea de Servicios y Distribuciones) against the Directorate General of Pharmacy and the Spanish Medicine Agency because they did not answer his request for protection of the wholesalers’ right to be supplied by pharmaceutical companies. The wholesaler also requested the imposition of a penalty on the company which denied him the supply.

The TSJM rejected all the arguments of the wholesaler and concluded that the law does not establish in any way a general or absolute right for wholesalers to be supplied by pharmaceutical companies. The court considered that the wholesalers’ right to be supplied which is contemplated in article 70.2 of Law 29/2006, of 26 July, must be interpreted in the light of article 68.1 of such law, which establishes that pharmaceutical companies may distribute medicinal products directly or through wholesalers. Therefore, the wholesaler’s right to be supplied depends on whether the pharmaceutical company uses its services for the distribution of its medicines.

Furthermore, the TSJM considers that although shortage of supply of some medicines has been proven, there is no evidence that such shortage was brought about by an incorrect distribution by the pharmaceutical company.



## The liability of the service provider and the Directive on liability for defective products

*Judgment of the CJEU of 21 December 2011, case C-495/10, Centre hospitalier universitaire de Besançon v Thomas Dutrueux and Caisse primaire d'assurance maladie du Jura*

### Background

During a surgery performed in a French hospital, a patient suffered burns caused by a defective heated mattress. The hospital was ordered to pay compensation to the patient and to the insurance company of the Jura region.

The hospital lodged an appeal against this judgment with the Conseil d'État arguing that the court had founded its sentence on a principle included in the French jurisprudence which according to the hospital would be contrary to Directive 85/374/EEC regulating the liability for damage caused by defective products. The principle in question points out that any public hospital service is objectively liable for the damage suffered by its patients due to defects in the equipments used during the healthcare assistance.

The Conseil d'État decided to make a reference for a preliminary ruling by the Court of Justice of the European Union, in order to clarify whether or not the liability of a services provider is included in the scope of Directive 85/374/ECC, when a service provider causes damages to the recipient of the services due to a defect in the equipments used for the provision of the services.

### Compatibility of the different regimes of objective liability

The Court of Justice of the European Union reminds that the purpose of Directive 85/374/EEC is to achieve a full harmonization of the legal provisions of the Member States regarding producer liability (or, in certain limited cases, importer and supplier liability) for the damage caused due to defects in their products.

According to the Court of Justice of the European Union the liability of a service provider for damage caused by the use of a defective equipment does not fall within the scope of Directive 85/374/EEC, since the service provider cannot be considered neither to be a producer, nor an importer nor a supplier of the defective product.

However, the existence of national rules that establish the liability of the service provider for damage caused by the use of a defective product does not affect negatively neither the effectiveness of Directive 85/374/EEC nor the objectives that it pursues and therefore its existence is in accordance with the European Union law. However, this national regime cannot be an obstacle to the application of the liability regime of the manufacturer established in the Directive and it has to acknowledge that both the person who suffered the damage as well as the service provider are entitled to claim liabilities from the producer of the defective product, as long as the requirements established to such effect in the Directive are fulfilled.



## Obtaining adequate informed consent is essential in order to prevent liabilities

### *Judgment of the High Court of Justice of La Rioja, of 17 October 2011, on the liability of the Administration for damage caused by the administration of a medicine*

#### Background

Last month an interesting judgment of the High Court of Justice of the region of La Rioja was made public. This judgment stresses once more the importance of adequately documenting the informed consent of the patient with the aim to prevent the possible claim for liabilities for damages caused by the administration of a medicine.

In particular, the court ruled on the claim of a patient that wanted to be indemnified by the healthcare Administration of La Rioja against a movement disorder supposedly caused by the administration of a medicine.

#### Requirements for the indemnity

The court starts by reminding that three necessary requirements must be fulfilled in order to be able to claim the Administration's liability for the damages caused as a consequence of the administration of a medicine in a public healthcare centre: (i) the existence of an actual damage, (ii) the existence of a cause-effect relation between the administration of the medicine and the damage and (iii) the illegality of the injury, that is, that the subject is not under the legal obligation to bear such damage.

The basic criterion to determine whether we are dealing with a damage that the patient has no obligation to bear is the "lex artis" criterion. This criterion implies that healthcare personnel

is not under the obligation to achieve a positive result for the patient, but to act with the diligence and the caution required by the circumstances of the case taking into account the current scientific knowledge.

#### The informed consent is an essential element of the "lex artis"

The court considers that in order to comply with the "lex artis" rule it is necessary that the healthcare personnel informs the patient about the diagnosis of the disease, the prognosis that may be expected from the treatment as well as the risks of the treatment, in such a way as to allow the patient to freely choose from the possible options including the option of not undergoing any surgery or treatment.

The judgment is also interesting as to the assessment of the proof on the relation of causality between the intake of the medicine and the damage suffered: the court modulates the burden of proof which falls on the plaintiff and it deems that the causal link has been proven since the Administration against which the claim was brought was not able to offer a satisfactory explanation for what happened.

The absence of the informed consent of the patient together with the causal relationship between the medicine and the ailments of the patient lead the court to conclude that he has suffered an indemnifiable moral damage as his right to self-determination regarding his healthcare was frustrated.



## 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.