



The rules on misleading advertising help to overcome the difficulties to criminally prosecute falsified medicines

Judgment of the Criminal Court of Madrid of 4 July 2014

Background

In this case, the court analyzes whether the commercialization and advertising of Bio-Bac, which started in Spain in the 90s could be criminally prosecuted. Bio-Bac was a compound of proteins and amino-acids which was marketed at the offices of some doctors and also directly to consumers through internet. The information which was given to the consumers presented it as having certain therapeutic properties and as efficient to treat several diseases, such as cancer, aids, hepatitis or arthrosis, among others.

The Spanish administration succeeded in withdrawing the product from the market. Its rulings were based on the idea that the product could not be presented as a medicinal product nor as a magistral formula because its efficacy, safety and quality had not been demonstrated.

Crime against public health

Once the administrative case was over, the matter reached criminal court. Under the Criminal Code, presenting a product as a medicine is a crime if, by doing so, the life or health of the individuals is put in danger. For the crime to exist, therefore, two conditions must be met: fraud and risk to the life or health of the individuals. In this case, the Court accepts that fraud existed, because the product was presented as being a medicinal one without having been approved as such.

As regards the second condition, the Court recalls the case law of the Supreme Court under which the life or the health of the individuals is

put in danger if a product has damaging effects or if it replaces conventional medical treatment. In the case that we are considering, the Court understood that none of the consumers of Bio-Bac suffered damages and, because of this, it considered that no crime against public health existed.

Misleading advertising as a crime

On the other hand, the Court considered that, when commercializing Bio-Bac, article 282 of the Criminal Code was infringed. Under this provision, those who make false allegations in their offers or advertising of products or services, in such a manner that gross damage may be caused to consumers, may be punished with imprisonment of 6 months up to a year, or with a fine.

In order to consider that misleading advertising crime has existed, it is not necessary to cause damages, it is sufficient that the false or misleading advertising may cause gross prejudice to the consumer. The court in this case understands that the consumers bought the product on the basis of misleading advertising, and therefore a crime existed under this provision.

On the other hand, the Court takes into account that the profits that the company obtained as a result of marketing Bio-Bac would have been much less if the product had been marketed as a food supplement, and understands that the economic damage caused to consumers was real.