Capsulas

New business models, appropriate instruments to channel innovative public procurement

Executive summary of Jordi Faus's presentation at the Pharmaceutical Law Course organized by Fundación CEFI

This article summarizes the main ideas presented at the round table on new business models of the Pharmaceutical Law Course.

First. In the field of medicinal products for hospital use, the migration from the supply of products to the provision of services is already a consolidated fact. This trend is expected to expand and to come close to offering the necessary services to manage a specific therapeutic situation. In any of these areas, and in today's world where data is a valuable asset, one cannot consider new models without the exchange of information between the relevant stakeholders.

Second. Analyzing any new model, in the area in question, from a legal perspective essentially poses two types of challenges: those inherent to the regulatory environment (on the one hand, if it cannot be done, it is necessary to justify why; on the other hand, if it can be done, it is necessary to explain under what conditions) and those related to the limits imposed by the regulations on public contracts.

Third. Public authorities must act in accordance with the precautionary principle and ensure protection against the risks posed by private activities; but they must also respect the principle of proportionality and the principle of favor libertatis, as set out in various European and Spanish regulations, including the Law no. 14/1986 on General Health. Note that, according to Article 25 of Law no. 14/1986, the intervention of the Public Administration, including in the health sector, must be conducted ensuring that "the regime that is established is adequate to guarantee the protection of public health, does not exceed what is necessary for this purpose and cannot be substituted by other less restrictive measures that lead to the same result". In addition, this law also states that "the procedures and formalities for obtaining authorizations or registrations (...) must be clear and unequivocal, objective, transparent and proportionate to the purpose of health protection". Furthermore, the principle that everything that is not expressly prohibited is permitted must be observed.

Fourth. The current version of the Public Sector Contracts Law, which applies to medicinal products, offers valid mechanisms for companies and contracting bodies to make proposals beyond traditional supply models. Improved complementary services that are of equal nature as the purpose of the main contract may be offered; moreover, mixed contracts are a possibility for other types of services. The agreements provided for in the Public Sector Contracts Law, or classic forms of patronage, may also be used.

Fifth. European case law endorses the notion of public procurement based on functionality and objectives rather than on personal elements. Not all legal relationships, which include a consideration, between companies and contracting authorities constitute a public contract, as stated in Falk Pharma, judgment of 2 June 2016. The purpose of public procurement rules is to ensure that the choice of supplier (which entails offering exclusivity) does not favor one company to the detriment

of another. Therefore, if the public authority does not face any choice of suppliers nor any granting of exclusivity, if there is no competition (as is the case for exclusive innovative medicinal products), the contract to be entered into may fall beyond the rules relating to public contracts.

In a nutshell, we clearly face a complex issue and it is possible, convenient and necessary for the managing entities of the NHS to focus on the envisaged legally protected interest: the achievement of positive health results by guaranteeing fair competition between companies. Any project based on these ideas ought to be legally feasible.

°°°°°