

ARTÍCULO ORIGINAL

**Potential impact of European decisions and reports in pharmacy planning
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ABSTRACT

Currently there are several cases in the field of the European Union regarding Spanish legislation on private pharmacy planning. The first of these cases was initiated by issuing a reasoned opinion by the European Commission on 28 June 2006. The second approach has taken place through the various preliminary questions raised before the Court of Justice of the European Communities by certain Spanish courts. Although not all of the above procedures have been completed, certain European pronouncements do provide what might be the consequences that they may have on the Spanish legislation on the subject. It is very likely that the binomial property-ownership in favor of pharmacists and planning criteria established in the Spanish regulations is considered compatible with European law. On the contrary, it is feasible that certain aspects of the merit scales applied by the Autonomous Communities for awarding newly authorized community pharmacies must be changed.

KEYWORDS: pharmaceutical regulations, European Union, legislation.

1. INTRODUCTION

The European Union (EU), through its organs and in conjunction with the successive treaties, has become unique law source in the world that is positioned between the international and national law. The membership of the Kingdom of Spain to the EU implies that the national law is subject to European regulations in the areas of competence of the EU, set out in the Lisbon Treaty 13 December 2007, ratified by Instrument of 26 September 2008, and specified for certain issues in Community law. On the other hand, the judicial power of the EU, represented by the Court of Justice of the European Union (hereinafter ECJ) has supranational scope hence configured as last resort in matters of EU competence.

It is well known that the EU influences over important issues such as the single currency, macroeconomic policy, working conditions, taxes, approval of products or agricultural policy. This fact allows close cooperation between its members allowing competition in a globalized world. However, each country has the capacity to make its own decisions in many other areas.

With respect to pharmacy issues, the EU has approved very important rules regarding

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medicines (marketing authorization procedures, for example) and the qualification of professionals. Only very recently, there have been statements of certain European institutions concerning private community pharmacies (CP) and their planning within Member States (MS). In particular, in connection with Spain, EU institutions have commented on Spanish CP planning regulations in two cases.

The first of these cases was initiated by a reasoned opinion (RO) issued by the European Commission on 28 June 2006. The second issue has been operated through questions to the Court of Justice (ECJ) by two Spanish courts: (i) Asturias Superior Court of Justice, and (ii) the Court of Contentious Administrative of Granada.

2. REASONED OPINION OF THE EUROPEAN COMMISSION

In order to address the content of the RO issued by the European Commission and understand its scope, the procedure needs to be seen in the context of the infringement proceeding by means of which the European Commission reviews acts or omissions of MS and is intend to determine whether these acts violate or not Community law. It is the main instrument the Commission has in order to ensure compliance with Community law.

The RO belongs to the first of the two phases in which the infringement procedure is split: the administrative phase. This phase begins with a formal notice by means of which the Commission refers to the MS when it is aware that the MS has breached its obligations, it describes the alleged infringement and requests a reply from the MS within a given term. If the MS does not answer or the explanations and arguments are not satisfactory to the Commission or the alleged infringement persists, the Commission issues a RO in which it warns the MS to end the infringement within a specified period. The MS reply to the Commission will be considered by the College of Commissioners in order to determine the case's closure or, should it consider that the infringement is maintained, the beginning of the second stage of the infringement proceeding, that is, the contentious stage, in which the European Commission begins a lawsuit against de MS before the ECJ. At this stage, if the ECJ declares the existence of an infringement, the MS concerned is obliged to adopt the necessary measures for the execution of the judgment.

In the present case, through the RO directed against Spain, the Commission questions the compatibility of certain aspects of Spanish pharmaceutical planning regulations with the freedom of establishment enshrined in art. 49 TFEU. More specifically, it considers that there are three points included in Spanish law that violate the provisions of Community law:

- (i) The CP ownership regulations which restrict the said ownership to pharmacists and excludes the possibility that a single pharmacist or several pharmacists jointly, own more than one CP simultaneously. In this regard, the Commission believes that measures less restrictive of the freedom of establishment (e.g. requiring the presence of a qualified professional, establishing certain liability standards or professional liability insurance) would achieve the same objectives as
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those pursued by such restrictions;

(ii) The CP health planning based on population and distance criteria. The Commission considers these criteria to be disproportionate and self-defeating in their intent to reach an adequate supply of medicines throughout the country, and

(iii) The procedures for CP authorization established by the Autonomous Communities, to the extent that some of these regions, such as Valencia, give priority to pharmacists who have gained their professional experience in the same region. This criterion is considered contrary to the principle of equality.

If the only EU ruling was the RO, the potential impact on Spanish pharmaceutical planning regulations could be multiple.

The acceptance by the Spanish State of the contents of the RO or any ECJ ruling in the line established by the Commission in the RO would involve the derogation of several rules:

(i) The Act 14/1986³ of 25 April of General Health, which establishes in article 103 that "pharmacies will be subject to health planning in the terms established by special legislation of medicines and pharmacies" and that "only pharmacists may own pharmacies open to the public and accredited to operate";

(ii) The Act 29/2006⁴ of 27 July of Guarantees and Rational Use of Medicines and Health Products, whereby "The Health authorities will carry out the planning of private pharmacies and must take into account the following criteria: a) General planning of the pharmacies in order to ensure appropriate pharmaceutical care" (article 84); and

(iii) The Act 16/1997⁵ of 25 April of Private Pharmacy Services Regulation, whose contents are configured as basic state legislation on health, which provides in article 1 that "pharmacies are health facilities of public interest subject to planning by the Autonomous Communities, in which the pharmacist-owner (...)" in its article 3 that "the territorial planning of pharmacies shall follow demographic and geographic criteria" and article 4 provides that "the sale and purchase of pharmacies may only take place in favour of one or more pharmacists".

In addition, it would also affect the CP planning regional regulations enacted by the Autonomous Communities in exercise of the powers attributed by their respective Statutes of Autonomy. For example, Act 6/1998⁶ of 22 June, of Pharmacy Planning of the Autonomous Community of Valencia, that states that "Only pharmacists may own and be accredited to operate community pharmacies open to the public" (article 9) and determines, following the guidelines established by Act 16/1997, a CP planning based on demographic and geographic criteria, and describes the basis of the authorization procedures of new CP (articles 16 et seq.).

However, the fact is that although the RO has not yet reached the judicial stage of the infringement procedure, there are rulings of the ECJ regarding the ownership of CP. Rulings

of 19 May 2009⁷ of the ECJ solve two sets of legal issues relating to the ownership of CP in Italy and Germany. The conclusions contained therein may be extrapolated to the case against Spain to the extent that they were issued by the same body, which would resolve if the Commission chose to continue the infringement procedure against Spain.

Specifically, in the aforementioned rulings, the ECJ concluded that the legislation under which the MS restricts the ownership of CP to graduates in pharmacy "is adequate to ensure the achievement of the objective of guaranteeing a safe and high-quality supply of medicines to the population and, therefore, the protection of public health" and it is not contrary to the EC Treaty. Accordingly, the ECJ accepts the validity of a fundamental premise of the pharmaceutical planning regulation model in force in Spain without excluding other possible regulations, such as those in force in certain European States, which also allow achieving the same objectives. Therefore, based on the above arguments, it is unlikely that the RO may have an impact on the Spanish CP ownership regulations. There has been no ruling, however, about the possibility of possessing or not more than one CP.

The other two Spanish legislative aspects questioned in the RO (that is, CP health planning based on population and distance criteria and procedures for CP authorization), are linked to the preliminary questions submitted to the ECJ by various Spanish courts and are addressed in the next section of this paper. In any case, in the context of the RO, as in the previous case, we should wait for the response of the College of Commissioners.

3. THE PRELIMINARY QUESTIONS

The so-called preliminary question allows national courts of MS (by themselves or at the request of the parties) that are in any doubt about the interpretation or validity of an EU law, to ask the ECJ for advice. The ECJ itself has stated clearly that this procedure is a judicial cooperation mechanism whereby "national jurisdiction and the ECJ are called to contribute directly and reciprocally to the development of a decision" to ensure a uniform interpretation of European Union law.

The preliminary question procedure takes place in two stages: a written stage and an oral stage, which ends when the General Advocate responsible for studying the preliminary question reads his conclusions in an open session. While the conclusions of the General Advocate, although mandatory, are not binding on the ECJ in the ruling it issues and they constitute a proposition to the ECJ of the legal solution to the issue under question.

In Spain, three preliminary questions have been raised concerning pharmaceutical planning regulations. Chronologically, the High Court of Asturias has raised the first two. The Court of Administrative Litigation of Granada has raised the third preliminary question. By means of these preliminary questions, the Spanish courts have requested the ECJ's interpretation of Article 49 TFUE, which sets out the freedom of establishment.

3.1. Pharmaceutical planning criteria

All of the aforementioned preliminary questions challenge the validity of certain features of Spanish pharmaceutical regulations. In particular, the preliminary question raised by the High Court of Asturias refers to the compatibility of certain regional rules of Asturias and European law, while the preliminary question raised by the Court of Administrative Litigation of Granada refers directly to the National law.

The issues raised by the High Court of Asturias focus on three aspects of the Asturian pharmaceutical regulations in force at the time the question was brought by the plaintiffs (Decree 72/2001, 19 July, regarding private community pharmacies planning in Asturias): i) modules setting a population of 2800 inhabitants per CP; (ii) the requirement of a 250-meter minimum distance between pharmacies; and (iii) the contents of the merit scale established in order to access to ownership of newly authorized pharmacies.

The first two aspects are consistent with the provisions of Spanish State regulations (i.e. Law 16/1997 of 25 April 1997) and appear in the pharmaceutical regulations of most of Autonomous Communities, consistent with the issues raised by the broader preliminary question of the Granada court. These issues will be reviewed together, as far as possible. In connection with the Asturias matter, the judgement of the ECJ was issued on 1 June, whilst the preliminary question of the court of Granada is still in its written phase.

According to the interpretation of Article 267 TFEU, the preliminary ruling of an interpretation preliminary question to be given is binding to the judge who raised the question, namely the High Court of Asturias and the Court of Administrative Litigation of Granada, who will have to apply the European regulations in accordance with the interpretation given by the ECJ.

However, since there is no express regulation of the effects of preliminary rulings it is difficult to determine whether the binding effect of the preliminary ruling is extended to further cases in which the same European rule is applied (*erga omnes* effect). According to the ECJ, the preliminary ruling does not apply exclusively to the case that provides the framework for that specific preliminary question. The ECJ case law has acknowledged that its interpretation preliminary rulings have a general authority that reaches, in addition to the national court that raised the question, all other national courts. However, the ECJ considers that the authority of its preliminary rulings is not absolute because the national courts retain the power to formulate new preliminary questions, if they consider not to be sufficiently informed, or even when they consider appropriate a case law change.

Although the question referred by the Superior Court of Justice of Asturias refers to Decree 72/2001, the truth is that the European ruling itself establishes a clear link between that decree and the national legislation that adapted The Act 14/1986 of 25 April of General

Health and Law 16/1997. Because the pharmacy planning regulations of other Spanish regions also derive from the state Law, the findings contained in the preliminary ruling are easily extrapolated to the whole of the Spanish pharmaceutical planning regulations, both state and regional.

First, the decision notes that, in accordance with Art. 168 TFEU, paragraph 7, as explained by the jurisprudence of the ECJ, and the twenty sixth considering of the Directive 2005/36, the "Union law does not detract any of the competence of Member States (...) to make arrangements to organize health services such as CP. "

However, the ECJ recognized that it is for each MS to decide what level of protection of public health is to secure and how to achieve it. The ruling also highlights that following Directive 2005/36, when a MS selects the pharmacists to be appointed as head of the new CP, by an articulated opposition proceedings under a national system of geographical distribution, that MS may maintain the development of such examination and require it to nationals of other States, provided that the rules that regulate it are in conformity with Union law.

The ruling explains that the establishment of requirements related to population density and distance between CP, conducted by the Asturian-regulation and the rest of the Autonomous Communities, "is a restriction of freedom of establishment guaranteed by the Treaty". But the sentence considers that it may impose such restrictions if they meet certain requirements: (i) be applicable without discrimination on grounds of nationality, (ii) be justified by overriding reasons of general interest, (iii) be suitable for ensure the attainment of the objective pursued, and (iv) be limited to that necessary to achieve that goal

In relation to this, the ECJ has stated that the rules to the question discussed are applied without discrimination and the protection of public health in this case; ensuring a high-quality supply of medicines to the population may justify restrictions on freedom of establishment. Furthermore, the ECJ considers that the Asturian pharmaceutical legislation questioned is adequate to achieve this objective, for the following reasons: (i) the fact that some MS do not limit the number of CP that can be created on national territory does not mean that the highest standards of other States on this matter are incompatible with the Treaty, (ii) health service providers in the pharmaceutical field may be subject to planning, including the authorization if necessary to ensure "health care tailored to the needs population, covering the whole territory and taking into account the isolated geographic regions. " Accordingly, in requiring a certain number of people to authorize a new CP is, according to the ruling, "right to distribute the drug in a balanced way in the country, ensure the entire population and appropriate access to pharmaceutical care and, consequently, improve safety and quality of supply of medicines to the population." ECJ added that "a MS may prescribe additional requirements (...), for example, a requirement (...) which requires minimum distances between pharmacies," which "increases the certainty that patients will have a pharmacy next and, therefore, a quick and easy access to appropriate pharmaceutical

care. "

Nevertheless, the ECJ continues to examine the consistency of the standard to achieve the target set and points out that the uniform application of standards of population density and distance in the Asturias Decree, if applied strictly, could not ensure that purpose, because of the existence of areas with specific demographic characteristics. However, remember the sentence that the state regulations, which adopted the Decree 72/2001, and provides measures of adjustment in terms of population density requirements and minimum distance between CP. They must be the Spanish Court who verify whether these exceptions apply to areas that have specific demographic characteristics, ensuring consistency within the system.

Finally, on the basis that it is for MS to set the level of protection of public health to be achieved, points out the Judgement of the ECJ that it can be understood reached the fourth mentioned requirement and the restriction on freedom of establishment justified, considering that it do not impose more restrictions than necessary to achieve the objective of ensuring a safe and quality supply of drugs,

Achieved the four requirements of the European jurisprudence, it can be concluded that the challenged demographic requirements and minimum distance between CP, established in the regulation of pharmaceutical Asturias planning constitute a restriction on freedom of establishment and, however, is not contrary to Union Law.

To the extent that the Asturias legislation considered by the ECJ emanates from an identical state regulations which includes demographic requirements and minimum distances between CP, we understand that neither this nor any of the other autonomous communities regulations could be considered contrary to European law and, therefore, the question referred by the Court of Administrative Litigation of Granada will be resolved in identical terms to the question of Asturias.

Notwithstanding the foregoing, the Court of Administrative Litigation of Granada has decided to keep the question raised in its submission to the ECJ in relation to the arts. 2.3 and 2.4 of Act 16/1997 concerning population and minimum distances, since it considers that limiting the number of CP is disproportionate, even counterproductive in connection with the objective of good supply of medicines in the territory concerned . However, a change of policy of the ECJ does not seem likely.

3.2 Merit scales to access to ownership of newly authorized pharmacies.

The question raised to the ECJ by the Superior Court of Justice of Asturias, also raises the compatibility with European law on certain matters relating to the selection criteria for new OF authorized holders, such as the increase of 20% of professional qualifications obtained in this Autonomous Community, and the priority in case of match among several candidates, for pharmacists have played his practice in the area of the Principality of

Asturias.

It is interesting to relate the said Asturias merit scale with the merit scales established in other Autonomous Communities since the authorization procedures of new pharmacies are different in each Autonomous Community, consequence of the different statutes of autonomy. Although, in fact, only the Communities of Navarra and Catalonia have procedures which are substantially different from those followed Asturias.

In the remaining fifteen Autonomous Communities, authorization is preceded by the determination by the health administration the number of pharmacies required. Following that first stage comes the awarding of the newly authorized pharmacies to pharmacists by application of the mentioned merit scales, and finally, after the establishment of the new pharmacy is carried out, the inspection's visit gives way to approval and registration. The procedure is regulated either globally or in consecutive steps (see Appendix). However, the content of the merit scales differ significantly, especially in some of the points at issue.

The ECJ considered that the criteria that favor domestic pharmacists in respect of other MS, have a discriminatory nature, being contrary to freedom of establishment.

4. CONCLUSIONS

According to the ECJ case law cited there is no legal impediment to accept that the ownership of CP, as public health establishments, is reserved to pharmacists.

The ECJ has also accepted the compatibility with European law of demographic modules and minimum distances established in Spanish regulations for the approval of new CP, provided that such restrictions are likely to be modulated to suit geographical areas with particular demographic characteristics understood that the philosophy of ensuring access for all citizens to the pharmacy service as a protection of public health itself is an argument justifying such restrictions on freedom of establishment conferred by Article 49 TFEU.

There is, however, a major stumbling block referring to the award stage of the authorized CP resulting from some of the criteria included in the scales covered by the merit scales of various Autonomous Communities, which, according to recent case law of the ECJ can be considered discriminatory elements.

It is quite possible, therefore, that the only effect resulting from the above is the need to revise the merit scales to adjudicate new CP in order to avoid the inclusion of discriminatory aspects and make them consistent with the objectives pharmaceutical planning. Therefore, one can expect the other aspects of pharmaceutical regulations put into question by the European Commission through the reasoned opinion fail to thrive.
