Letter dated: 9 May 2013

From: Pío García-Escudero Márquez, President of the Spanish Senate

To: President Barroso

Outgoing Ref.: 006379

Sir:

I hereby inform you that, at its session on 7 May 2013, the Joint Committee for European Affairs approved Reasoned Opinion 2/2013 of the same Joint Committee, setting out the reasons why it considers that the amended proposal for a directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems [COM (2013) 168 final] [2012/0035 (COD)] (Dossier No 282/190) does not uphold the principle of subsidiarity.

I am forwarding this to you in accordance with the provisions of Protocols 1 and 2 of the Treaty of Lisbon and in the context of the political dialogue between national parliaments and the EU institutions.

Palacio del Senado, 9 May 2013.

Letter dated: 10 May 2013

From: Jesús Posada Moreno, President of the Spanish Congress of Deputies

To: President Barroso

Outgoing Ref.:018982

Sir:

I hereby inform you that the Joint Committee for European Affairs, at its session on 7 May 2013, approved Reasoned Opinion 2/2013 of the Joint Committee, setting out the reasons why it considers that the amended proposal for a directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems [COM (2013) 168 final] [2012/0035 (COD)] (Dossier No 282/190) does not uphold the principle of subsidiarity.

I am forwarding this to you in accordance with the provisions of Protocols 1 and 2 of the Treaty of Lisbon and in the context of the political dialogue between national parliaments and the EU institutions.

Palacio del Congreso, 9 May 2013.

REASONED OPINION 2/2013 OF THE JOINT COMMITTEE FOR EUROPEAN AFFAIRS SETTING OUT THE REASONS WHY IT CONSIDERS THAT THE AMENDED PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL RELATING TO THE TRANSPARENCY OF MEASURES REGULATING THE PRICES OF MEDICINAL PRODUCTS FOR HUMAN USE AND THEIR INCLUSION IN THE SCOPE OF PUBLIC HEALTH INSURANCE SYSTEMS[COM (2013) 168 FINAL] [2012/0035 (COD)]

BACKGROUND

A. The Protocol on the Application of the Principles of Subsidiarity and Proportionality, annexed to the Lisbon Treaty of 2007 and in force since 1 December 2009, has established a procedure enabling the national parliaments to examine the compliance of EU legislative initiatives with the principle of subsidiarity. This Protocol was transposed into Spanish law by Law 24/2009 of 22 December 2009 amending Law 8/1994 of 19 May 1994. In particular, the new Articles 3(j), 5 and 6 of Law 8/1994 form the legal basis for this Reasoned Opinion.

B. The amended proposal for a directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems was approved by the European Commission and sent to national parliaments, which have a period of eight weeks to check its compliance with the principle of subsidiarity. This period expires on 17 May 2013.

C. On 9 April 2013 the Bureau and Spokespersons of the Joint Committee for European Union Affairs agreed to examine the proposal, appointing Rubén Moreno Palanques as rapporteur, and asked the Government to draw up the report referred to in Article 3(j) of Law 8/1994.

D. A report has been received from the Government, stating that the proposed text breaches the subsidiarity principle and that, in Spain's case, this effect is especially serious for the sustainability of the National Health System, in that it deprives the Spanish Government of the possibility to develop evaluation mechanisms that are suited to its needs and financial capacities.

E. At its meeting on 7 May 2013 the Joint Committee for European Union Affairs approved the following

REASONED OPINION

1. - *Article 5(1) of the Treaty of the European Union states that 'the* use of Union competences is governed by the principles of subsidiarity and proportionality'. According to Article 5.3 of the same Treaty, *'the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level'*.

2. - The legal basis for the proposal analysed is Article 338(1) of the Treaty on the Functioning of the European Union:

"Article 114

1. Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Article 26. The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

4. If, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 36, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

5. Moreover, without prejudice to paragraph 4, if, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved.
When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.

7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure.

8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.

9. By way of derogation from the procedure laid down in Articles 258 and 259, the Commission and any Member State may bring the matter directly before the Court of Justice of the European Union if it considers that another Member State is making improper use of the powers provided for in this Article.

10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a Community control procedure. "

3. - According to its explanatory memorandum, the amended proposal for a directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems (hereinafter the proposal) aims to ensure that national measures to control the funding of medicines and manage their consumption in the framework of healthcare systems do not create trade barriers affecting the proper functioning of the internal market.

4. - The proposal is the result of a lengthy negotiating process that began more than a year ago. The European Commission approved its first proposal to repeal Directive 89/105/EEC on 1 March 2012. After the text had been discussed, and amendments had been tabled to it, by both the European Parliament and the Council, the Commission decided to amend its original proposal. This amended version is the document which has been submitted for assessment of its compliance with the subsidiarity principle.

5. - The proposal contains 22 articles detailing various legal, regulatory or administrative measures of national, regional or local scope whose purpose is to control the prices of medicinal products for human use and to determine which products are covered by public health insurance systems, as well as to what extent and under what conditions they are covered. In accordance with Article 1 the following are excluded from the scope of the proposal:

a) voluntary contractual agreements which are concluded between competent public authorities and the marketing authorisation holder for a medicinal product, which is not mandatory nor represents the only possibility for the medicinal product to be included in the health insurance systems, and which aims to include a medicinal product under the scope of a health insurance system while monitoring elements are agreed upfront among both parties relating to the effectiveness and/or relative efficacy of the given medicinal product, with a view to enabling the effective provision of that medicine to patients under specific conditions and during an agreed period of time.

b) national measures intended to determine the prices or the coverage of medicinal products by public health insurance systems which are subject to national or Union legislation on public procurement.

6. - Chapter II of the proposal includes various measures designed to regulate the procedure for pricing medicinal products. Article 3 lays down basic rules governing the procedure for approving the market prices of the products. The chapter also establishes rules relating to the procedure for price increases, and for price freezes and reductions, in Articles 4 and 5 respectively. Lastly, Article 6 contains rules relating to controls on the profits of persons responsible for placing medicinal products on the market.
The fundamental principles underpinning these provisions are objective decision-making by the authorities competent in the field of pharmaceuticals, and the establishment of strict compliance procedures, including time limits which, as stated in the exploratory memorandum, are designed to bring more legal certainty to the market.

7. - Chapter III concerns the procedures for including medicinal products in, or excluding them from, health insurance systems. It contains provisions on the classification of medicinal products with a view to their inclusion in health insurance systems, and measures to control or promote the prescription of specific medicinal products. The provisions are again designed to prevent the measures adopted by national authorities from interfering in the functioning of the internal market.

8. - Chapter IV, which is entitled ‘specific requirements’, contains general implementing provisions in respect of the procedures covered in the directive. There are provisions on the effectiveness of the time limits, additional proof of quality, safety, efficacy or bioequivalence, and the general principle of non-interference with intellectual and industrial property rights.

9. - Chapter V contains three articles designed to ensure that the procedures covered by the directive are transparent. The articles provide that civil society organisations must be consulted, including patient and consumer groups, and other interested parties; that decision-making bodies and prices must be transparent, and that national authorities must draw up and submit to the Commission a report on the application of the time limits.

10. - The proposal's compliance with the subsidiarity principle should be assessed on the basis of Article 168(7) of the Treaty on the Functioning of the European Union:

> 'Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.'

11. - A reading of Article 168(7) TFEU in conjunction with the principles underpinning the Union's internal market (in particular Article 26 TFEU) leads us to the conclusion that, in this field, an appropriate balance needs to be struck between the safeguarding and development of the internal market, on the one hand, and Member States' right to define their own health policies and to organise and deliver health services and medical care, on the other. On this basis, it is clear that Member States cannot completely disregard their internal market obligations when drawing up national health policies on pharmaceutical products. At the same time, however, Union provisions on the internal market should not deprive Member States of the tools needed to define their own health policies, including, as in this case, the right to influence the prices of medicinal products and to decide which pharmaceutical products are covered by their public health systems.

12. - In view of the above, it is important to assess to what extent the proposal succeeds in striking a balance between compliance with internal market principles and respect for national competences. On the one hand, the Commission's move to amend the original proposal so as to increase the time limits given to national authorities for approving the prices of medicinal products and including a product in health insurance systems should be viewed positively. The same can be said of the attempt to do away with certain bureaucratic procedures found in the original proposal, such as the requirement for Member States to notify their intention to adopt measures which fall within the scope of the Directive. These changes to the proposal will make it easier for Member States to exercise their competences in the fields of health policy and provision of medical services.

13. - However, other parts of the proposal impose a considerable burden on national authorities as regards the exercise of their competences in the health field. Possibly the best example is Article 11, which limits Member States' capacity to adopt measures to control or promote the prescription of specific medicinal products.

14. - At this time of economic crisis, measures to limit spending, cost-effectiveness considerations and budgetary implications become increasingly important. Interference in Member State policies relating to the pricing of medicinal products and their inclusion in public health insurance systems could thus be seen as one step too .

15. - The proposal also fails to explain sufficiently why Member States would be unable, with a more flexible regulatory framework, to achieve the internal market development objectives pursued by the Commission. Whilst there are some serious shortcomings in the way Directive 89/105/EEC is implemented, given that it entered into force almost 25 years ago and does not reflect the current reality in the pharmaceutical market, the full development of the internal market could be achieved in this field by means of a directive which encroaches less on national competences.

16.- In trying to strike the necessary balance between the safeguarding and development of the internal market, on the one hand, and the right of Member States to define their own health policies, on the other, this proposal encroaches too much on the latter. By restricting to such an extent Member States' capacity to price medicinal products and to decide whether to include them in public health insurance systems, the proposal infringes on national competences in the field, and thus breaches the principle of subsidiarity.

CONCLUSION

For the reasons stated above the Joint Committee on European Affairs considers that the amended proposal for a Directive of the European Parliament and of the Council on the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems does not comply with the principle of subsidiarity as laid down in the current Treaty on European Union. .

This reasoned opinion will be forwarded to the European Parliament, the Council and the European Commission, within the framework of political dialogue between the national parliaments and the institutions of the European Union.