# R E A S O N E D  O P I N I O N

**of the Standing Sub-Committee on European Union Affairs**
**17 April 2012**

**pursuant to Article 23g (1) of the Austrian Constitution in conjunction with Article 6 of Protocol No.2 on the Application of the Principles of Subsidiarity and Proportionality**

**COM (2012) 84 final**
Proposal for a Directive of the European Parliament and 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

## A. Reasoned Opinion

The draft under consideration is incompatible with the principle of subsidiarity.

## B. Grounds for Reasoned Opinion

On 1 March 2012, the European Commission tabled its proposal to change the rules for the inclusion of medicinal products in the reimbursement code of the public health insurance systems of the Member States. According to information provided by the Commission, its proposal is aimed at facilitating the functioning of the internal market for medicinal products by modernising the current provisions of Directive 89/105/EEC, shortening deadlines and introducing sanctions as well as a notification procedure.

As specified in Article 168, paragraph 7, of the Treaty on the Functioning of the European Union (TFEU), the organisation and financing of public health care are within the competence of the Member States. With this in mind, the Court of Justice of the European Union in its jurisprudence referred to the fact that maintaining the financial balance of public health insurance systems and preserving a high level of public health care are justified reasons for the application of particularly stringent controls and standards in these areas. Moreover, the Court of Justice underlined that the influence of the European Union on the organisation of health insurance systems must be limited to a minimum level. However, the proposal now on the table would undermine the responsibility of the Member States for their health care systems and is therefore considered to be unacceptable.

Although the proposal does not provide for the harmonisation of rules on pricing and cost reimbursement, it contains far-reaching and largely excessive provisions regarding the procedure to be applied, which ultimately would have a significant impact on the decision-making scope of national health policies. Calculations performed by the Austrian Federation of Social Insurance Institutions have come to the conclusion that shortened deadlines and, consequently, less time for the negotiation of adequate prices would result in losses of up to EUR 3.2 million per year and negotiating procedure for public health care systems. Moreover, the sanctions provided for in the proposal (penalty payments, damages) would tend to be to the unilateral advantage of the pharmaceutical industry from the very outset of the negotiations, which would result in further disadvantages for public health insurance systems.

In many cases, delays in the inclusion of medicinal products in the scope of national health insurance systems are due to incomplete information submitted by the applicants. Sufficient time should be available for the pharmacological, therapeutic and economic assessment of the products concerned, if the high level of quality of the health care system is to be guaranteed. The Committee therefore rejects the proposed shortening of deadlines as well as the introduction of sanctions, as these would not generate any European added value.
The legal basis chosen by the Commission exclusively refers to Article 114 TFEU concerning the internal market. However, Articles 7 ff. of the proposal undoubtedly interfere with the right of the Member States to organise their systems of statutory health insurance, as provided for by Article 168, paragraph 7, TFEU, and other articles. Hence, the legal basis chosen by the Commission is insufficient. The very fact of an insufficient legal basis implies, however, that the Commission is overstepping the powers conferred to the Union by virtue of that legal basis. If the Union is overstepping its conferred powers, the competence of the Member States is inadmissibly restricted, which, by necessity, constitutes a violation of the subsidiarity principle.

Moreover, the provisions of the proposed Articles 11, 13, 15 and 16 are to be regarded as an inadmissible interference with the constitutional autonomy of the Member States to determine their own law-making procedures. In addition, they are superfluous for the achievement of the objective of the Directive. In particular, the notification procedure newly introduced in Article 16 restricts the leeway of the national legislator to an extent that is absolutely incompatible with the provisions of Article 168, paragraph 7, TFEU, and the decisions of the Court of Justice.

In Article 14 on non-interference of intellectual property rights, the proposed directive provides for administrative procedures instead of court procedures and states that intellectual property rights are to be disregarded. This provision is impossible to reconcile with Article 6 of the European Human Rights Convention regarding the right to a fair trial in civil rights matters as well as Article 1 of the 2nd Protocol to the European Human Rights Convention and Article 17 of the European Fundamental Rights Charter regarding the protection of property. The Treaties have not conferred upon the Union the power to restrict the rights granted by the EHRC or the EU Fundamental Rights Charter. Article 14 therefore is in violation of the aforementioned rights.

In conclusion, the Committee wishes to point out that a mere reference to the impact assessment regarding compatibility with the principle of subsidiarity violates Article 5 of the Protocol on the Application of the Principles of Subsidiarity and Proportionality, which provides for a detailed statement making it possible to appraise compliance with the principle of subsidiarity to be included in the draft itself. In the proposal now on the table, even the statements in the impact assessment are insufficient. Referring to the internal market alone does not constitute a sufficient basis for compliance with the principle of subsidiarity. If, however, a proposal for a legal act of the Union, contrary to the provisions of the Treaties, lacks a substantive and sufficient justification of compliance with the principle of subsidiarity, the procedure provided for scrutiny by the national parliaments cannot be performed on a factual basis compliant with the Treaties. Thus, the provisions relating to the procedural aspects of the principle of subsidiarity are being violated and the proposed legal act is at risk of becoming fundamentally and irreparably null and void.