



**THE SENATE  
OF THE PARLIAMENT OF THE CZECH REPUBLIC  
8<sup>TH</sup> TERM**

**645<sup>TH</sup>**

**RESOLUTION OF THE SENATE**

Delivered on the 23<sup>rd</sup> session held on 14<sup>th</sup> June 2012

**on the 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 /Senate Press no. N 152/08/**

**The Senate**

**I.**

**1. Is aware**

of the need to modernize the legal framework of economic competition in the market of medicinal products for human use while maintaining the highest possible protection of the health of patients;

**2. Reminds**

that Article 168 of the Treaty on the functioning of the European Union recognizes the responsibility of the Member States for their health policies and for the organization and supply of health care, which also includes the aspect of distribution of financial resources;

**II.**

**1. Is of the opinion**

that any measure of the Union imposing specific obligations on the Member States in the field of organization of state power, the regulation of administrative proceedings and the administrative judicial review represent a significant intervention into the competences and the constitutional autonomy of the Member States and, therefore, should be thoroughly reasoned from the perspective of its compatibility with the principle of proportionality, so that it is obvious, that the stated goal cannot be achieved by using more moderate measures conserving the competences of the Member States;

**2. Therefore assesses**

that the proposed legislation creating an independent institution monitoring adherence to the time limits concerning the inclusion of drugs into health insurance systems lacks a solid justification concerning the compatibility with the

principle of proportionality, its conception disrupts the legal system of the Czech Republic, and hence causes legal uncertainty;

**3. Recalls**

that according to article 288 of the Treaty on the Functioning of the European Union and according to the principle of subsidiarity, stated in Article 5 paragraph 3 of the Treaty on the European Union, the Member States are provided substantial discretion when implementing directives into domestic law; this discretion is limited only by the requirement of compatibility of implementation measures with EU law;

**4. Considers therefore**

the proposed mechanism of notifications of national measures to the European Commission as problematic, since according to Article 16 of the draft directive the Member States would be obligated to take into account the remarks of the European Commission even if their proposed measures in the field of registration and rating of medicines were not in conflict with EU law;

**5. Points out to the fact**

that with regard to the arguments mentioned above the European Commission may not limit the discretion of national institutions with regard to the application of Article 16 of the draft directive, concerning the choice of the means to achieve the goals of the directive, and may not attempt to indirectly harmonize the laws of the Member States beyond the wording of the directive;

**6. Does not support**

the significant shortening of deadlines for decision-making in national proceedings, as proposed in the draft directive, since these deadlines could only be adhered to through a significant reinforcement of the personnel of national administrations, which would entail disproportionate administrative costs;

**7. Disagrees**

with the unilateral transfer of responsibility for delays in the drug registration proceedings on governmental institutions, who may not always be the only culprit of the non-observance of the deadline;

**III.**

**1. Requests**

the Government to inform the Senate about the way this position was taken into account and to provide the Senate with further information on the proceeding of negotiations;

**2. Authorises**

the President of the Senate to forward this Resolution to the European Commission.

Milan Štěch  
sign manual  
President of the Senate

Adolf Jílek  
sign manual  
Senate Verifier