Courtesy translation

OPINION

of

THE SENATE OF THE REPUBLIC OF POLAND

of 29 March 2012.

on the incompatibility with the principle of subsidiarity of the proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards information to the general public on medicinal products subject to medical prescription
COM/2012/048
and
of the proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 as regards information to the general public on medicinal products for human use subject to medical prescription
COM/2012/049,

The Senate, after having scrutinised the proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards information to the general public on medicinal products subject to medical prescription, COM/2012/048, and the proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 as regards information to the general public on medicinal products for human use subject to medical prescription, COM/2012/049, has concluded that these proposals are incompatible with the principle of subsidiarity as set out in Article 5 (3) of the Treaty on European Union.

As regards the objective of ensuring a high quality health care for patients, the European Commission did not demonstrate why it considered appropriate only the information that would reach patients in accordance with the requirements established at the European Union level. The European Commission only acknowledged the existence of differences between Member States in access to information and did not explain in what situations these disparities might have a negative impact on patients. Taking into

consideration the migration of patients from one Member State to another does not alter the fact that it has been and will be the responsibility of a physician to inform about the effects of the prescribed medicine and the way of its application.

As regards the objective of the elimination of barriers to free trade in medicinal products between Member States, the European Commission did not demonstrate why the lack of a harmonized system for informing the public might constitute a barrier to trade between Member States. The sale of a medicine has depended and will continue to depend on whether it was granted a marketing authorisation in a particular country or at the EU level, and it is the physician who decides about the prescription of a particular medicine. The European Commission also failed to demonstrate that the existing rules constituted a barrier to free trade between Member States and that the objectives of the proposals could not be achieved by the Member States themselves.

The adoption of these proposals may also allow the circumvention of the ban on advertising prescription-only medicines through disseminating information about them over the Internet.

Moreover, it should be noted that the adoption of the proposed solutions would result in the need to develop a complicated system of monitoring information about prescription-only medicines, which would involve costs for the Member States disproportionate to vague benefits arising from the proposals. Therefore, there is no added value justifying the proposed amendments.

Thus, the European Commission did not convincingly explain in what way the proposed legislative acts would contribute to the achievement of the intended objectives. Additionally, it did not demonstrate that the existing provisions had not ensured their sufficient realisation, nor that the given objectives could not be achieved by the Member States themselves.

MARSHAL OF THE SENATE

Bogdan BORUSEWICZ