EUROPEAN COMMISSION

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Mr Bogdan BORUSEWICZ
Marshal of the Senate
Ul. Wiejska 6
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Dear President,

The Commission would like to thank the Senát for its reasoned Opinion on the proposals for a Directive of the European Parliament and the Council amending Directive 2001/83/EC as regards information to the general public on medicinal products subject to medical prescription {COM(2012)48 final} and for a Regulation of the European Parliament and the Council amending Regulation (EC) 726/2004 as regards information to the general public on medicinal products subject to medical prescription {COM(2012) 49 final}.

When adopting the original Commission proposals {COM(2008) 663 final and COM(2008) 662 final} in December 2008, the Commission published the corresponding impact assessment. This impact assessment remains relevant for the amendments proposed on 24 November 2010, about which the Senat issued a reasoned opinion. It aims to explain the consistency of the general objective of the initiative with other EU policies and horizontal objectives. In particular section 2.6 addresses the right of the EU to act[1].

The impact assessment explained that the disparities between Member States might have a negative impact on patients. In particular, EU legislation harmonises the way key information on medicinal products is drafted (summary of product characteristics and package leaflet) and makes these documents the key tools to promote the proper and rational use of medicines among healthcare professionals and patients. In a system where the rules on the authorisation of medicines and on product information are fully harmonised to ensure the same level of protection of public health across the EU, this objective risks to be undermined by widely divergent national rules on the dissemination of such key information by marketing authorisation holders.

[1] Section 2.6 Does the EU have the right to act? Treaty legal basis and subsidiarity

Harmonised provisions could allow citizens in all Member States to have access to the same type of information disseminated by the marketing authorisation holders on prescription-only medicines based on a common set of quality criteria. This has become increasingly critical with the adoption of the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare[2]. Indeed, this Directive introduces the principle of recognition of prescriptions, which allows for medicinal products prescribed in one Member State to be dispensed in another.

The proposals do not allow for the circumvention of the ban on advertising of prescription-only medicines through the dissemination of information over the internet. They foresee a number of safeguards in terms of what information may be circulated and how it is controlled, in order to ensure full respect of the ban of direct-to-consumer advertising.

The Commission's proposals set out rules for the control of the information, and provide for compulsory pre-control in most cases. From the discussion in the European Parliament, this appeared necessary in order to ensure appropriate protection of patients.

I hope that these clarifications address the comments and concerns raised in the reasoned Opinion submitted by the Senát.

I look forward to continuing our constructive political dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President

[2] OJ L88 of 4.04.2011, p. 45.