EUROPEAN COMMISSION

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Dear President,

The Commission would like to thank the Senato della Repubblica for its Opinion on the amended 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} and on the Commission proposals for a Directive of the European Parliament and the Council amending Directive 2001/83/EC as regards pharmacovigilance {COM(2012) 52 final} and for a Regulation of the European Parliament and the Council amending Regulation (EC) 726/2004 as regards pharmacovigilance {COM(2012) 51 final}.

As regards information on medicinal products to the general public, the Commission would like to underline that the requirements of the respective articles are cumulative. Indeed Article 100d lays down the quality criteria of the information that can be made available, while Article 100b lays down the content of the information and Article 100c the medium through which the information is made available. The quality criteria are applicable to the information that can be made available via internet or certain printed materials.

The aim of the proposals is to provide a clear framework for provision of information by marketing authorisation holders about their prescription-only medicines to the general public. Therefore, only the information that would fulfil the requirements provided by the new title, would be authorised information, as opposed to banned advertising and non-authorised information. Indeed, the Commission considers that it is more workable and appropriate to define authorised information than to provide an abstract definition of information.

As regards the control of the information, the Commission's amended proposals provide for compulsory pre-control in most of the cases. The Commission believes that these amended proposals would guarantee an adequate control of the information that is made available.

Sen. Renato SCHIFANI
Presidente
Senato della Repubblica
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The Senato della Repubblica expresses doubts regarding the perception of the information by the non professional public. The Commission considers that healthcare professionals are important interlocutors. The amended proposals concern medicinal products under prescription; therefore the interaction between the patients and their doctors/pharmacists will continue to exist.

On pharmacovigilance, the Senato della Repubblica recommends to adopt measures to promote more widespread and focussed research into and testing of pharmaceutical products for paediatric use. The Commission considers that with the Paediatric Regulation (EC) No 1901/2006, Union legislation already provides for a targeted and specific tool to stimulate adequate research, with the appropriate system of obligations and rewards/incentives for pharmaceutical undertakings to do so.

The Commission also takes note of the Senato della Repubblica's view that measures should be adopted to overcome limits concerning gender profiles, determined by the insufficient level of research into and testing of pharmaceutical treatments for women. In this regard the Commission would like to highlight that individual case safety reports on adverse reactions to a medicinal product, which have been prepared in accordance with the current legislation, will contain information about the age and gender of the patient concerned. This information allows to identify and assess issues that have different impacts in relation to the gender or age of the patient concerned.

I hope that these clarifications address the comments and concerns raised by the Senato della Repubblica and look forward to continuing our political dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President