EUROPEAN COMMISSION

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Dear President,

The Commission would like to thank the Sénat for its 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}.

The Sénat considers that the added-value of the proposals for European citizens is not justified by the expected cost of the pre-control and of continued monitoring by competent European and national authorities. The Commission would like to recall that Member States presently already have to ensure the respect of rules regarding the ban of advertising to the general public and to the health professionals of medicinal products available only on medical prescription. Without harmonisation of the information requirement, the effect of the control would remain limited to each Member State and would thus not benefit the others. Therefore, the Commission believes that by harmonising rules on information requirements, administrative burden could actually be reduced.

The impact assessment accompanying the original proposals makes apparent that the quality of content and the choice of information channel could have a critical impact upon how increased patient information about medicinal products affects health outcomes and the cost of public healthcare delivery. The Commission remains convinced that ensuring high quality of information, provided by coherent application of clearly harmonised defined standards across the EU, would be beneficial to European patients.

The Sénat also considers that as Member States do not agree on a common distinction between advertising and information, they should remain responsible for determining the quality criteria of the information. The Commission would like to emphasise that the proposals' aim is to define a clear framework for the provision of information by marketing authorisation holders about their prescription-only medicines to the general public. Only the information that would fulfil the requirements, in particular quality criteria, provided by the new title introduced by the Commission proposals, would be authorised information, as opposed to banned advertising and non-authorised

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information. Indeed, the Commission considers that it is more appropriate and in particular more workable, to define authorised information than to provide an abstract definition of information.

The Commission is also convinced that in order to preserve the effectiveness of the EU pharmaceutical acquis as regards advertising, the issue of information provision should also be addressed at EU level. Indeed, as Directive 2001/83/EC lays down detailed restrictions on advertising and excludes certain types of information from these restrictions, any national rules prohibiting or unduly restricting such information could alter the balance introduced by the Directive.

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

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

Yours faithfully,

Maroš Šefčovič
Vice-President