



EUROPEAN COMMISSION

Brussels, 20.07.2012  
C(2012) 5095 final

Dear President,

*The Commission would like to thank the Chambre des députés 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}.*

*As regards your concern that in the absence of a clear distinction between advertising and information, industry could influence the public, the Commission does not consider that defining the notions of advertising and of information would be a solution. Indeed, a grey zone would still exist regarding information that is allowed and that which is not. Therefore, the proposals do not provide such a definition, but rather describe directly the information that would be allowed. This is the information that respects the requirements of the new title introduced by the Commission proposals regarding content, quality, channel and control mechanisms of the information.*

*The Chambre des Députés is also concerned about the creation of an excessive administrative burden. 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. However, without harmonisation of information requirements, the effect of the control would be limited to each Member State and would thus not benefit the others. Therefore, the Commission believes that by harmonising rules on information requirement, administrative burden could actually be reduced.*

*I hope that these clarifications address the comments and concerns raised in the opinion submitted by the Chambre des Députés.*

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

*Yours faithfully,*

*Maroš Šefčovič  
Vice-President*

*M. Laurent MOSAR  
Président de la Chambre des Députés  
Rue du Marché-aux-Herbes 23  
L-1728 Luxembourg*