



## EUROPEAN COMMISSION

Brussels, 13.3.2015  
C(2015) 1615 final

*Dear Presidents,*

*The Commission would like to thank the Congreso de los Diputados and the Senado for its Opinion on the proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency {COM(2014) 557 final} and on the proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products {COM(2014) 558 final}.*

*The Commission welcomes the observations and comments made by the Congreso de los Diputados and the Senado, in particular that the Congreso de los Diputados and the Senado consider that the two proposals are in line with the principle of subsidiarity set out in the current Treaty on European Union.*

*The Commission would like to make the following remarks on the comments provided by the Congreso de los Diputados and the Senado:*

*The needs of the veterinary sector differ substantially from those of the human sector in relation to medicines. In particular, the drivers for investment for the human and the veterinary medicines markets are different. The size of the animal pharmaceutical industry is only a small fraction of the size of the pharmaceutical industry for human medicines. The Commission therefore finds it appropriate to develop a regulatory framework addressing the characteristics and specificities of the veterinary sector, which cannot be considered as a model for the human medicines market.*

*The Commission would like to stress that the revision of the legislation on veterinary medicinal products aims to ensure the highest standards of public health, animal health and environmental safety while at the same time increasing the availability of veterinary medicinal products and reducing unnecessary administrative burden.*

*The points made above are based on the initial proposal presented by the Commission which is currently in the legislative process involving both the European Parliament and the Council in which your government is represented.*

*Mr Jesús POSADA MORENO  
President of the  
Congreso de los Diputados  
Floridablanca s/n  
E – 28071 MADRID*

*Mr Pio GARCÍA-ESCUADERO MÁRQUEZ  
President of the Senado  
Plaza de la Marina Española, 8  
E – 28071 MADRID*

*The Commission hopes that these clarifications address the issues raised by the Congreso de los Diputados and the Senado and looks forward to continuing our political dialogue in the future.*

*Yours faithfully,*

*Frans Timmermans  
First Vice-President*

*Vytenis Andriukaitis  
Member of the Commission*