Summarised report

REPORT 43/2014 BY THE JOINT COMMITTEE FOR EU AFFAIRS, DATED NOVEMBER 18, 2014, ON THE COMPLIANCE WITH THE PRINCIPLE OF SUBSIDIARITY BY THE FOLLOWING PROPOSALS:

- 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 MEDICAL PRODUCTS FOR HUMAN AND VETERINARY USE AND ESTABLISHING A EUROPEAN MEDICINES AGENCY (TEXT WITH EEA RELEVANCE) [COM (2014) 557 FINAL] [2014/0256 (COD)]

- REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON VETERINARY MEDICINAL PRODUCTS (TEXT WITH EEA RELEVANCE) [COM (2014) 558 FINAL] [2014/0257 (COD) {SWD (2014) 273 FINAL} {SWD (2014) 274 FINAL} {COM (2014) 558 FINAL/2 ANNEXES}

BACKGROUND

A. The legal basis of this report is to be found in articles 3 j), 5 and 6 of Act 8/1994 (amended by Act 24/2009) regulating the compliance with the principles of subsidiarity and proportionality in Spain.
B. The deadline to verify the compliance with the principle of subsidiarity by this Proposal is November 26, for the Regulation on Medical Products for Humans, COM (2014) 557 and November 27, for the Regulation on Veterinary Medicinal Products, COM (2014) 558.
C. A report by the Government has been requested and MP Mr. Alejandro Alonso Núñez has been appointed as rapporteur for the subsidiarity report on this initiative.
D. The Government states in its report that the proposal complies with the principle of subsidiarity.
E. The Cortes of Castilla y León state in its report that the proposal complies with the principle of subsidiarity.
F. The Assembly of Extremadura states in its report that this proposal complies with the principle of subsidiarity.
G. The Joint Committee for EU Affairs adopted on November 18, 2014, the following:

OPINION

1. Article 5 (1) of the Treaty on the European Union indicates that "*the use of Union competences is governed by the principles of subsidiarity and proportionality*", and adds in Article 5 (3) of the same Treaty that "*under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall only act in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level".*

2. The legislative proposal considered is based on articles 114 and 168 b) and c) of the TFEU.

3.- Work on a European legal framework for veterinary medicinal products started in 1965 with the adoption of Directive 65/65/EEC, which required that marketing authorisations be issued before such products could be placed on the market. In 2011, all the rules on production,

marketing, distribution and use were consolidated in a veterinary medicines code (Directive 2001/82/EC); this was followed by Regulation (EC) No 726/2004, which incorporated all provisions related to veterinary medicinal products.
Stakeholders and Member States have expressed concern that the current legislation does not fully deliver a single market in veterinary medicinal products and fails to meet the Union's needs, and they have indicated the following areas for improvement: regulatory burden, the lack of availability of veterinary medicinal products, especially for small markets such as that for bees, and the functioning of the internal market. They proposed a full review of the 2011 Directive and related legislation with a view to establishing an updated legislation, adapted to the veterinary sector, and thus increase the availability of these medicinal products, reduce the administrative burden, stimulate competitiveness and innovation and address the public health risk of antimicrobial resistance.

The public consultation "Better regulation of veterinary pharmaceuticals: how to put in place a simpler legal framework, safeguarding public and animal health while increasing the competitiveness of companies", was launched on 13 April 2010. The Commission's Impact Assessment Board (IAB) released its final opinion in September 2013.

On the basis of these reports, the Commission proposes a separate regulation by means of Regulation 726/2004 (focused on medical products for humans) and the Regulation on veterinary medicinal products. The Commission justifies its proposal given the specificity of veterinary medicinal products, with a very fragmented market and a different price-setting mechanism.

The legal basis for both provisions is to be found in article 114 and 168.4.b) of the TFEU. The Commission has likewise informed that the costs for the Agency shall be covered by the proposed review of fees.

The rapporteur stresses that the Government of Spain states in its report Spain's concern in the sense that the separate regulation of human and veterinary medicinal products be incompatible with the priorisation of public health criteria and with the message of the Commission "Animals + Humans = One Health". Therefore, it states that it would rather have a common regulation. The assessment procedure for veterinary medicinal products is the same as the one for medical products for human, but as regards the latter we must also bear in mind the eventual consequences for human and animal public health and the environment. Therefore, the Government of Spain would like to express its concern in the sense that a separate legislation might be guided by economic and productive concerns rather than health principles.

However, the Joint Committee considers that the proposal complies with the principle of subsidiarity, since the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level.

CONCLUSION

For the aforementioned reasons, the Joint Committee for EU Affairs considers that this Proposal complies with the principles of subsidiarity and proportionality laid down in the Treaty on the European Union in force.