(Summarised report)

REPORT 40/2014 BY THE JOINT COMMITTEE FOR EU AFFAIRS, DATED OCTOBER 22, 2014, ON THE COMPLIANCE WITH THE PRINCIPLE OF SUBSIDIARITY BY THE PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF MEDICATED FEED AND REPEALING COUNCIL DIRECTIVE 90/167/EEC (TEXT WITH EEA RELEVANCE). [{COM (2014) 556 FINAL] [2014/0255 (COD)] {SWD (2014) 271 FINAL} {SWD (2014) 272 FINAL} COM (2014) 556 FINAL 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, 11, 2014.
C. A report by the Government has been requested and Senator Mr. Juan Ramón Represa Fernández has been appointed as rapporteur for the subsidiarity report on this initiative.
D. The Government states in its report that this proposal complies with the principle of subsidiarity.
E. The Joint Committee for EU Affairs adopted on October 22, 2014, the following:

OPINION

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 43 and 168 (b) of the TFEU:

3. The aim of the legislative proposal considered is to repeal Directive 90/167/EC, which laid down the conditions for the manufacture, placing on the market and use of medicated feed within the Union. This Directive gave freedom to Member States regarding interpretation and implementation of the legal provisions, but this flexibility has contributed to some problems among them. Therefore, the objective of the proposal is to harmonise at a high safety level the manufacture, marketing and use of medicated feed and intermediate products in the EU and to reflect technical progress in this field, as well as the setting up of rules for the adoption of delegated acts and of implementing acts.

4. The pursuit of a high level of protection of human health is one of the fundamental objectives of EU food law (including the provisions on the placing on the market and use of medicated feed), being the protection of animal health likewise one of its general objectives. It is proposed that medicated feed be manufactured only with authorised medicinal products according to the law and by authorised manufacturers. The proposal includes measures such as the prohibition of the preventive use of medicated feed or the establishment of limits to the residues of veterinary

medicines in feed within the EU. The proposal for legislative modernization includes in its scope the medicated feed for pets.

5. The proposed Regulation allows and regulates the anticipated production of medicated feed and the mobile and on-farm mixing. The provisions include measures for disposal of not used medicated feed on farm. EU wide limits will be set for the carry-over of veterinary medicines in feed. Specific rules for the prescription, the validity of the prescription, the use of medicated feed containing antimicrobials in food-producing animals. For veterinary medicinal products authorised at national level, the Regulation sets Intra-Union rules for trade of medicated feed.

6. The Regulation includes five chapters, namely "Scope and Definitions", "Manufacture, storage, transport and placing on the market", "Approval of establishments", "Prescription and use" and "Procedural and final provisions". Likewise, it includes six annexes on: a) Requirements for feed business operators, b) Incorporation of the veterinary medicinal product into the feed, c) Labelling particulars, d) Permitted tolerances for the compositional labelling of the medicated feed or intermediate products, e) Prescription form and f) Correlation table.

7. Spain, France and Germany lead feed manufacturing within the EU. An updated regulation, protecting security and efficiency in medicated feed and facilitating the work of farmers and authorities' control is therefore needed.

This Proposal is crucial for Spain, since, within the therapeutical alternatives available to veterinarians, medicated feed are the most commonly used. The incorporation of the medicinal products into the feed makes it easier to treat larger groups and guarantees and homogenous mix.

8. This legislative measure falls within the realm of shared competences. The Proposal complies with the principle of subsidiarity, since the goals of the proposed action cannot be sufficiently achieved by the Member States (either at central level, or at regional or 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 subsidiarity and proportionality principles laid down in the Treaty on the European Union in force.