SENATE OF THE REPUBLIC

XVII LEGISLATURE

Doc. XVIII No 82

RESOLUTION OF THE 12th[a] PERMANENT COMMITTEE

(Hygiene and health)

(Rapporteur VALDINOSI)

approved at the sitting of 25 November 2014

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

THE PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON VETERINARY MEDICINAL PRODUCTS (COM(2014) 558 FINAL)

Pursuant to Article 144(1) and (6) of the Rules of Procedure

Communicated to the President's Office on 27 November 2014

TIPOGRAFIA DEL SENATO

I N D E X

The Committee,

having examined in conjunction acts COM(2014) 557 and 558 final;

whereas those acts are related and concern the same subject-matter, inasmuch as:

COM(2014) 558 final puts in place, while safeguarding public health, animal health, food safety and the environment, an up-to-date, proportionate body of legislation tailored to the specificities of the veterinary sector, aiming to: increase the availability of veterinary medicinal products, reduce administrative burdens, stimulate competitiveness and innovation, improve the functioning of the internal market and address the public health risk of antimicrobial resistance;

COM(2014) 557 final amends Regulation (EC) No 726/2004 in order to take account of the fact that, by virtue of the provisions in COM(2014) 558 final, centralised marketing authorisation for veterinary products is being decoupled from that for medicines for humans,

whereas the aims pursued by the acts appear to be sound;

considering that those acts comply with the principles of subsidiarity and proportionality, subject to the observations set out below;

considering that the legal basis of the two proposals is correctly identified by the Commission in Article 114 and Article 168(4) of the Treaty on the Functioning of the European Union (TFEU), which contain provisions on the establishment and functioning of the internal market and the approximation of relevant legal, regulatory and administrative provisions and cover measures in the veterinary field directly aimed at protecting public health, setting high standards of quality and safety for medicinal products and devices for medical uses;

having regard to the observations of the 14th Committee;

having considered the reports to the Parliament concerning such acts, prepared by the Ministry of Health and sent, pursuant to Article 6(4) of Law No 234 of 24 December 2012, to the Department for European Policies of the Prime Minister's Office;

expresses, in respect of both acts, a favourable opinion as regards compliance with the principles of subsidiarity and proportionality, with the following observations:

In respect of COM(2014) 558 final, it is submitted that the cases of delegation of powers referred to in Article 135 (in conjunction with Article 146) and Article 84(3) (in conjunction with Article 87-*ter*) exceed the lawful scope of operation of the delegation of power provided for in Article 290 of the TFEU since they cover 'essential elements' of a legislative act and therefore should be laid down in full during the ordinary legislative procedure, thus allowing – also in future – the national parliaments to intervene in accordance with the procedure referred to in Protocol No 2 annexed to the TFEU on the application of the principles of subsidiarity and proportionality; that intervention, on the other hand is precluded for the delegated acts procedure. There is also the aggravating circumstance that that preclusion would be for the same indeterminate period of time as the delegation itself (Article 146(2) and Article 87-*ter*(2)). Notwithstanding that these cases relate to 'essential elements', it is possible that a delegation of power phased over a period of five years, subject to a single renewal for the same period, following a report from the Commission, would be less prejudicial to the prerogatives of national parliaments. At the end of the period, the monitoring powers provided for by Protocol No 2 would become available;

in respect of COM(2014) 557 final, given that that act does not have the the prescribed justification with regard to the principles of subsidiarity and proportionality, concerning the fees laid down in Article 70 of Regulation (EC) No 726/2004, cited above, the overall financial impact of the proposal is unclear. An in-depth analysis is therefore necessary, also in light of the new activities provided for in the proposal for a regulation in COM(2014) 558 final and as stated in the Communication from the Commission, Programming of human and financial resources for decentralised agencies 2014-2020 (COM(2013) 519) in which, in view of the phasing in of additional activities assigned to the European Medicines Agency under the major revision of the pharmacovigilance legal framework in 2010, which is applicable as of July 2012 (Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 and Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010), additional fees were proposed, with the contribution to the EU budget remaining broadly unchanged;

also expresses a favourable opinion on the substance of the legislative package under consideration, since it agrees with the aims underpinning them, with the following conditions:

1) the provision on direct sale of medicinal products by the veterinarian must be deleted, since it is necessary to retain a clear distinction between the roles of persons prescribing and persons selling pharmaceutical products, and

at the same time the veterinarian's rights and duty to hold the necessary stocks of medicinal products should be established (in Italian the '*armadietto*' (cabinet))

2) it is necessary to clarify that veterinary medicinal products may be prescribed exclusively by veterinarians, since the wording of Article 110(2) of COM(2014) 558 final is ambiguous where it states that the party entitled is the 'person qualified to do so in accordance with applicable national law';

3) provision for the possibility of online sales of veterinary medicinal products must be reviewed, since this is a source of potential misuse and needs specific analysis and regulation;

4) as regards combatting the development of resistance, the phenomenon needs to be addressed also in relation to antiviral and pesticide products; furthermore, relevant control activities must be conducted not only at European level but also by individual Member States;

5) as for the withdrawal period, some aspects of the set of rules in Article 117 of COM(2014) 558 final must be revised, in particular those relating to the standardised correction factor for derogating uses of veterinary medicinal products, which might not be sufficiently precautionary regarding the risk of residues in foodstuffs of animal origin;

6) in the context of the abovementioned lack of clarity about the overall financial impact of the acts in question, there is a need for further analysis of the burden arising from the new pharmacovigilance procedures, which confer on the European Medicines Agency (EMA) the task of managing a database of adverse events, working together with the competent authorities of the Member States (while the current position in Italy is that the Ministry of Health assesses the periodic safety reports submitted by pharmaceutical companies, notifications of adverse events and safety monitoring at national level); it should be taken into consideration in this regard that centralising the activities concerned under the responsibility of the EMA does not reflect a similar strengthening of the national regulatory authorities;

7) it is necessary to simplify and facilitate the use of homeopathy, including in the veterinary field.

OPINION OF THE 14th[a] PERMANENT COMMITTEE

(EUROPEAN UNION POLICIES)

(Rapporteur: COCIANCICH)

25 November 2014

The Committee,

having completed its examination of the acts COM(2014) 557 and COM(2014) 558 final,

with reference to the proposal for a regulation in COM(2014) 558 final;

whereas:

- the proposal puts in place, while safeguarding public health, animal health, food safety and the environment, an up-to-date, proportionate body of legislation tailored to the specificities of the veterinary sector, aiming to: increase the availability of veterinary medicinal products, reduce administrative burdens, stimulate competitiveness and innovation, improve the functioning of the internal market and address the public health risk of antimicrobial resistance;

- it therefore repeals and replaces Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products. The proposal in the related act COM(2014) 557 amends Regulation (EC) No 726/2004 of the European Parliament and of the Council of 21 March 2004 in order to take account of the fact that centralised marketing authorisation for veterinary products is being decoupled from that for medicines for humans, which continue to be governed by Regulation (EC) No 726/2004;

- the proposal lays down rules for obtaining a marketing authorisation, specifying that the product in question can be marketed for the approved indications only;

- various marketing authorisation procedures are provided for: a centralised procedure, in which the Commission grants an authorisation; procedures in which Member States grant the authorisation; a national procedure; a mutual recognition procedure; and a decentralised procedure. Regardless of whether the authorisation is obtained at Union or national level, the requirements for the safety, efficacy and quality of the product are the same;

- it establishes a single product database for all authorised veterinary medicinal products in the Union. Competent authorities will be obliged to upload data on national marketing authorisations;
- post-marketing authorisation measures include amending marketing authorisations and monitoring products after they have been on the market (pharmacovigilance);
- there are also provisions on the supply and use of veterinary medicinal products after a marketing authorisation has been granted, new restrictions on the supply of antimicrobial veterinary medicinal products and rules on prescriptions and online sales of veterinary medicinal products;
- inspections by Member States' competent authorities should ensure that the Union rules are complied with and enforced at national level. The Commission will be able to check Member States' inspection systems to ensure that the legislation is enforced consistently;
- in Article 146 of the proposal, the Commission is empowered to adopt delegated acts in a series of cases, including those concerning the initiation, duration, time-limits and conduct of the imposition of fines or periodic penalty payments to the holders of marketing authorisations granted under the Regulation, the maximum amounts of those penalties as well as the conditions and methods for their collection (Article 135);

noting, as regards the principles of subsidiarity and proportionality, that in the view of the European Commission:

- the requirement(s) to be met by the legislative initiative in the short or long term (the first criterion to be examined in assessing compliance with the subsidiarity principle) are stated as being that the legislation on veterinary medicinal products has been criticised by the pharmaceutical industry, veterinary surgeons, farmers and general public organisations as not adequate to the needs of the veterinary sector. Those stakeholders have indicated that the current legislation is disproportionate and burdensome, and not conducive to innovation.

The impact assessment in document SWD(2014) 274 final states that veterinary medicine is private medicine and therefore product development by the industry is driven by successful returns on investments. The veterinary pharmaceutical market is a multi-species and a pluri-national market. Furthermore, the requirements and procedures for obtaining a marketing authorisation to a veterinary medicine and for keeping it on the market are complex and generate administrative burdens to the pharmaceutical industry (estimated to be of 13% of the total turnover of the sector). These factors, and a legislation which is not suited to innovation, interfere with returns to investments and are at the root-problem of the lack of available authorised veterinary medicines.

There is in fact an overall problem regarding availability at EU level of veterinary medicines for minor species, rare or emerging diseases and for the treatment and prevention of some diseases in major species. This lack of veterinary medicinal products poses significant problems, for example poorer animal health and welfare, increased risks for human health, and economic and competitive disadvantages for EU farming. There is therefore a requirement to review the legislation to modernise it and make it tailor-made to the needs of the sector;

- the added value of EU involvement (second criterion to be examined in assessing compliance with the subsidiarity principle) is based on the fact that the current EU legislation on veterinary medicinal products has brought some harmonisation to the procedures and rules required to place veterinary medicinal products on the EU market, but there is evidence that the existing provisions do not deliver a functioning internal market.

Diverging or incomplete transposition of the rules and the existence of numerous national requirements imply that companies are confronted with different rules and interpretation in countries and have also led to different levels of public and animal health protection. It is critically important to have a single market for veterinary medicinal products as the veterinary pharmaceutical sector is driven by commercial returns obtained through the sales of veterinary medicinal products on the resources spent. The current confined and fragmented markets do not allow the pharmaceutical sector to have a positive return on investments for developing new products for certain animal species. The ambition to improve the availability of medicines in the Union and the functioning of the internal market and market competition can only be carried out at EU level;

- accordingly, the package comprising COM(2014) 557 and 558 is proposed. The package 'would deliver a total reduction of administrative burdens to the industry of at least 145.4 million euros per year' (SWD(2014) 274):

with reference to the proposal for a regulation in COM(2014) 557,

whereas:

- the EU Regulation, which will be the final act of the examination procedure of COM(2014) 558, provides for centralised marketing authorisation for veterinary products, involving the need to repeal the similar parts of Regulation (EC) No 724/2004, cited above, which governs the same authorisations and which, after amendment, will apply only to authorisations of medicines for humans;

- in addition to those amendments of a formal nature, the proposal introduces provisions on the costs of the procedures and services

associated with the operation of the Regulation, which are to be recovered from those making medicinal products available on the market and from those seeking authorisation.

Article 67 of Regulation (EC) No 726/2004 is amended to provide that the revenue of the European Medicines Agency is to consist of a contribution from the Union and 'fees paid by undertakings for obtaining and maintaining Union marketing authorisations'. The new Article 70 confers on the Commission the power to adopt implementing acts which specify 'the structure and the level of the fees and charges referred to in Article 67' and 'the services for which charges may be collected'. It is therefore stated that the costs for the Agency for implementing and applying the new rules are entirely covered by fees charged to industry;

- in the proposal, the new Article 87b of Regulation (EC) No 726/2004 confers on the Commission the power to adopt delegated acts in a series of cases, including establishing the list of obligations under the Regulation, the infringement of which may be subject to financial penalties, the procedures for the exercise of the Commission's powers to impose fines or periodic penalty payments, and 'elements to be taken into account by the Commission' when imposing fines and setting their maximum amounts (Article 84(3));

- having considered the reports to the Parliament concerning the acts under consideration, prepared by the Ministry of Health and sent, pursuant to Article 6(4) of Law No 234 of 24 December 2012, to the Department for European Policies;

- considering that the legal basis of the two proposals is correctly identified by the Commission in Article 114 and Article 168(4) of the Treaty on the Functioning of the European Union (TFEU) concerning legislative measures on animal health, which are essential to public and animal health, environmental protection, trade and single market policy;

comments favourably, within its area of responsibility, as regards compliance with the principles of subsidiarity and proportionality, in accordance with Protocol No 2 annexed to the TFEU, making the observations below:

- in respect of the proposal for a regulation in COM(2014) 558, it is submitted that a regulation is the most suitable legal form for ensuring effective harmonisation of the provisions in force, whereas in respect of COM(2014) 557 the choice is consistent with the act which is amended, that is to say, Regulation (EC) No 726/2004.

It is submitted that the cases of delegation of powers referred to in Article 135 (in conjunction with Article 146) of COM(2014) 558 and Article 84(3) (in conjunction with Article 87-*ter*) exceed the lawful scope of operation of the delegation of power provided for in Article 290 of the TFEU since they cover 'essential elements' of a legislative act and therefore should be laid down in full during the ordinary legislative procedure, thus allowing – also in future – the national parliaments to intervene in accordance with the procedure referred to in Protocol No

2 annexed to the TFEU on the application of the principles of subsidiarity and proportionality; that intervention, on the other hand is precluded for the delegated acts procedure. It should also be noted that that preclusion would be for the same indeterminate period of time as the delegation itself (Article 146(2) and Article 87-*ter*(2) of the proposal).

Notwithstanding that these cases relate to 'essential elements', it is possible that a delegation of power phased over a period of five years, subject to a single renewal for the same period, following a report from the Commission, would be less prejudicial to the prerogatives of national parliaments. At the end of the period, the monitoring powers provided for by Protocol No 2 would become available;

- as regards the proposal in COM(2014) 557, it should be noted that the act sent to national parliaments pursuant to Protocol No 2 has no justification with regard to the principles of subsidiarity and proportionality. Article 5 of the Protocol requires that any draft legislative act should contain a detailed statement making it possible to appraise compliance with the principles of subsidiarity ad proportionality;
- concerning the fees laid down in Article 70 of Regulation (EC) No 726/2004, relating to the subject-matter of the proposal in COM(2014) 557, the overall financial impact of the proposal is unclear. An in-depth analysis is therefore necessary, also in light of the new activities provided for in the proposal for a regulation in COM (2014)558 final and as stated in the Communication from the Commission, Programming of human and financial resources for decentralised agencies 2014-2020 (COM(2013)519) in which, in view of the phasing in of additional activities assigned to the European Medicines Agency under the major revision of the pharmacovigilance legal framework in 2010, which is applicable as of July 2012 (Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 and Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010), additional fees were proposed, with the contribution to the EU budget remaining broadly unchanged.

Finally, we have concerns about the recent judgment of the Civil Service Tribunal of 13 November 2014 in Case F-2/12 which cancelled the appointment of the executive director of the European Medicines Agency, of Italian natonality, on purely formal grounds.

€1.00