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Statement on the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on veterinary medicinal products /* COM/2014/0558 final - 2014/0257 (COD) */

CAM animal practitioners/Tierheilpraktiker (CAM stands for complementary and alternative mdicine) regard themselves as a member of a regulated animal health profession. The activities of the CAM animal practitioners in Germany are governed by numerous laws and provisions (inter alia by Medicines Act, the Animal Welfare Act, animal health law, Heilmittelwerbegesetz: medininal product advertisement law).

To the proposal, we express ourselves therefore as follows:

A. General

The European Commission has launched a proposal to amend resp. replace the previously existing law for veterinary medicinal products. Due to the existence of various animal species the legal situation of veterinary medicinal products is highly fragmentated. This has led to a variety of supplements and provisions which complicate the handling of law and partly contradict the rules and objectives of the internal market.

I. Approval

Against this background, the reorganization of the veterinary medicinal products legislation and the core objectives,

- Halting the use of antibiotics in animals, combat antimicrobial resistance in humans and animals,
- Improving the availability of veterinary medidinal products,
- Reducing the regulatory burden,
- Introduction of pharmacovigilance for use of medicinal products in animals,
- Stimulating competitiveness and innovation,

are absolutely to be welcomed from the viewpoint of CAM animal practitioners.

II. Critical Points

A closer examination of the proposal, however, reveals that some of its parts do not comply with the abovementioned objectives. Given a strict interpretation of significant passages the formulations even gets in complete contradiction to those objectives. Possibly due to inadvertent defective formulations there is a risk that a sensible and for most parts overdue change in the legislation, which is in the best interests of consumers and animals, is reversed to its opposite effect.

Below, we will comment on essential aspects according to our view:

1. The proposal's scope will in a problematic way also include substances, which merely serve for the prevention of disease or sustaining animal health care. Thus it extends the term “veterinary medicinal product” unduly and unjustifyingly.

2. Contrary to the intended purpose, the availability of complementary and alternative medical drugs for animals will be disproportionately restricted by the proposal.

3. The proposal insufficiently takes into account that animals as well as humans should have as possibly unrestricted access to a risk-free therapy diversity. This also includes complementary and alternative medical therapies.

4. The proposal's present design leads to a conflict with the constitutionally guaranteed freedom of profession according to Art.12 German Basic Law resp. Art. 15 EU Charter of Fundamental Rights. As far as the proposal's provisions intend to render impossible the exercise of the profession of a CAM animal practitioner or the raise of revenue from such an activity, there might be as much as an illegal interference with the right to an established and exercised business enterprise (Art. 14 Basic Law Germany), if not an act which will cause liability for damages or compensations.

5. With regard to homeopathic remedies, a general ban on the use of medicinal products for human use in animals is disproportionate in compliance with the EU regulation 37/2010.

6. There is a contradiction to the Council Regulation on organic production and labelling of organic products and repealing Regulation No 834/2007 (Article 14, Para. 1 e (ii), Art. 15 para. 1 f (ii)), according to which the treatment with complementary and alternative medicinal products (e.g. phytotherapeutic, homeopathic and other products) must take precedence over treatment with chemically synthesised allopathic veterinary medicinal products. There is no large-scale admission of complementary and alternative medical drugs for animals to be expected if they have already been authorized as medicinal products for human use.

7. We are concerned that the provisions requiring manufacturers to establish a pharmacovigilance system might lead to a conflict of interest.

III. Our demands/suggestions

1. In accordance with the Council Regulation on organic production and labelling of organic products and (EC) No 834/2007 (Article 14 para. 1 e (ii), Art. 15 para. 1 f (ii)), the treatment with be complementary and alternative medicinal products (phytotherapeutic, homeopathic and other products) must have priority over treatment with with chemically synthesised allopathic medicinal products. With regard to antimicrobial resistance prevention, this should not only apply to animals of biological-ecological livestock production, but for all the animals.

At the same time, the use of complementary and alternative medicinal products contributes to environment protection and achieving sustainability. The priority of using complementary and alternative medicinal products is even more important due to the fact that according to the proposal's provisions antimicrobial medicines in the future are no longer supposed to be usable in animal husbandry resp. livestock production (cf. recital No 37).

The production and use of complementary and alternative medicinal products provides a better guarantee for harmful substances not to accumulate in human and animal organism and the environment.

2. CAM animal practitioners (non-veterinarian and veterinarian) employ a wide range of therapeutics. These include homeopathic remedies, phytotherapy, leech, enzyme therapeutics et al.. Therefore, this broad range of non-prescription and complementary and alternative medicinal products should be preserved for all species including livestock, regardless of the dosage form and the storage conditions. Exercising complementary and alternative medical therapies must not only be left to physicians and veterinarians, as this would result in a loss of variety of methods as well as in a professional limitation of non-medical therapists, as noted under point II.4.

3. To answer risks there might exist concerning the use of homeopathic remedies – if there are any, provisions should adopt a so called first safe dilution (concept of “first safe dilution” or “safe only by dilution”), but not introduce prescription or separate/additional registration/authorization as veterinary medicinal products.

B. Special Section – Comment

1. We propose the inclusion of a new recital with the following version:
"In accordance with Council Regulation on organic production and labelling of organic products and repealing Regulation (EC) No 834/2007 and in compliance with the objectives of the prevention of antimicrobial resistance, promotion of animal health, food safety, environment protection and in terms of sustainability, the treatment with complementary and alternative medicinal products takes precedence over treatment with chemically synthesised allopathic veterinary medicinal products".

2. Recital 16
In terms of animal welfare and food safety there are no concerns whatsoever to apply homeopathic medicinal products that are registered for human use in animals, even in food-producing species, if and so far as other requirements acc. EU Regulation No. 37/2010 are fulfilled.

Insofar as homeopathic medicinal products medicines authorized for human use require a specific authorization procedure for the use in animals, there is a contradiction to the goal of fighting the lack of availability of veterinary medicinal products. If at all, risks arise by the potency resp. dilution, not by the substance itself.

EU regulation no 37/2010 has adopted safe potencies sufficiently. There is no reason for a separate authorization/registration for homeopathic remedies being required for the use in animals, nor will it improve food safety, especially since these medicinal products are recommended for pregnant women, nursing mothers, toddlers and infants.

3. Recital 17

Registered homeopathic medicinal products, as well as complementary and alternative medicinal products for human and veterinary use should be exempted from the requirement of authorization for off-label use.

Reason: see comments on the recitals 16 and 33..

4. Recitals 33-39

Prior to treatment of each organ system specific assessment should take place whether other measures are adequate in order to replace the use of antibiotics or minimize it. Therefore, complementary and alternative medicinal products should be given priority. t

Reason: see above A.III.1.

5. Recital 47

Continuous pharmacovigilance of veterinary medicinal products should be in the hands of a manufacturer-independent authority.

6. Recital 70

The coordination group should also include members with comprehensive knowledge in complementary and alternative therapies.

7. Recital 71

We are in favour to generally autohorize the use of homeopathic medicinal products for human use, including immunological homeopathic products, in all animals, expressively including food-producing animals. Possible risks should be taken into account by the establishment of safe potencies (dilutions).

Reason:

Homeopathic products do not harm humans nor animals. A compulsion to apply in animals only medicinal products authorized for the use in animals, is legally disproportionate. For manufacturers, the effort in order to obtain an additional registration/authorization for the use in animals is also economically disproportionate, because the medicinal products have already undergone appropriate assessments. With regard to homeopathic medicinal products, the purpose of the regulation, i.e. better availability of veterinary medicinal products, will be undermined by this provision. It is to be expected that once the regulation enters into force, there won't be more, but even less homeopathic remedies available on the market for the use in animals.

8. Art. 2 para. 4

a) Article 2, para. 4 should be supplemented by the following points:

"(f) substances or preparations of substances that are only intended to be applied externally on the animal for cleaning or care, or for influencing the appearance or body odor, as far as no substances or preparations are added which are excluded from marketing outside pharmacies.

(g) Biocidal products referred to in Art. 3 para. 1 letter a) Regulation (EU) No 528/2012 of

the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ. L 167, 27.6.2012, p.1)

(h) Animal feedstuffs in terms of Regulation (EC) No. 767/2009 of the European Parliament and the Council."

Reason:

The best way to avoid the use of drugs and therefore antimicrobial drugs in livestock, is not to give rise to health problems and diseases in the first place. Adequate and animal-friendly forms of animal husbandry, reasonable and balanced feeding and comprehensive advice to farmers are key parameters. And for good reason, German legislation on medicinal products has excluded the purpose of nutrition, care, influencing odor and taste, cleaning and biocides. This is only logical, since optimally designed feeding and care of animals will eliminate the breeding grounds for many diseases. The guiding principle of "precaution is better than aftercare" has been the basis for this legislation.

Art. 4 para. 1 of the proposal defines "veterinary medicinal product", whereas, at the same time, Art. 2 para. 4 lists exemptions from the scope of the regulation. Thus, the two provisions taken together, describe the scope of the regulation. There is a discrepancy in comparison to the currently applicable European law compliant version of the German Medicines Act (Arzneimittelgesetz/AMG). Up to now, § 2 para. 3 no. 4 - 6 German Medicines Act (AMG) lists exemptions from the definition of medicinal products for care substances, biocidal products and feedingstuffs. These exemptions from the scope of the regulation can't be found neither in the definition of the scope nor in the definition of "veterinary medicinal products"or among the exceptions. This means that substances which meet the definitions of § 2 para. 3 no. 4 - 6 German Medicines Act (AMG) will fall within the scope of the regulation in the future. This is supposed to result in a considerable restriction of the principle "precaution is better than aftercare" as well as to a considerable reduction of available products and substances used for the purpose of complementary and alternative therapies – which currently are not classified as medicinal products. This is contrary to the expressed objective of the regulation to increase the availability of medicinal products for animals.

<u>Cleansing and care products, feedstuffs</u>
Recital 4 of the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use states clearly that there was an agreement to exempt such substances and compositions from the definition als "medicinal product", which serve as food, feed and personal care products. This was taken into account by § 2 para. 3 no. 4 and 6 German Medicines Act (AMG). These excemptions should be included into the proposal either in Art. 2 (scope) or Art. 4 (definitions).

<u>Biocidal products</u>
The authorization and use of biocidal products is already regulated by the Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. This is taken into account by § 2 para. 3 No. 5 German Medicines Act (AMG).

The distinction between feed additives and medicinal products is formulated contradictory to the objectives in a way, that as a result, for example salads, fruit and herbs for animals may be marketed only as a medicinal product in the future, because their metabolic preventive and health impact, and thus their metabolic effect are well known and integral part of healthy animal feed.

b) We oppose to the proposal of the German Bundesrat (BR-Drucksache 420/1/14 of 26.1.2015 AV12) to include substances and articles that are intended to restore physiological functions by a physical effect into the scope of the regulation. It is legally disproportionate to submit products, which are already authorized for human use, to an additional authorization procedure. Authorization and assessment for human use is sufficient to minimize health risks for animals. A reference to products which are subject to the Medical Devices Act, should be sufficient.

9. Art. 5 para. 2

A permanent authorization we deem risky, provided that the manufacturers themselves will be responsible for the pharmacovigilance system, because conflicts of interest are to be expected. (s. Art. 72). A permanent authorization shifts the burden of proof from the manufacturer (currently manufacturers have to re-apply for each authorization every few years and to prove the safety of their product) to administration insofar as these will have to provide and prove reasons to withdraw a product authorization in the future. This shift of burden of proof is problematic inasmuch as according to Art. 72 No. 1, it is the manufacturers who are obliged to develop and maintain the system of pharmacovigilance. The marketing authorization holder thus would have it in his hand to provide, collect and evaluate the facts for a withdrawal or extension of authorization. This is incompatible with the objective of the regulation, i.e. to establish an effective phamacovigilance system.

10. Art. 29 para. 1 b, e

A general veterinary prescription for all veterinary medicinal products for food producing animals is destined to cut off the therapeutic basis of CAM animal practitioners, whose profession it is to treat these animals with complementary and alternative medicinal products and thus to contribute to the minimizing of the excessive use of antibiotics. CAM animal practitioners would also loose their livelihood regarding their professional perspective. This would be an infringement of Art. 12 of the German Basic Law and Art. 15 EU Charter of Fundamental Rights as well as Art. 14 of the German Basic Law.

11. Art. 29 para. 1 d

The provision is too vague and infringes the principle of legal certainty.

12. Art. 29 para 3

The provision entails the risk of inadequate restrictions on the use of complementary and alternative medicinal products. The preconditions required in paragraph 3 for non-prescription will be difficult to achieve in practice and only can be provided under a

disproportionate effort. It is a reversal of the current principle that for prescription certain requirements must be met.

In order to obtain the variety of complementary and alternative medical resources, their use in animals should generally remain non-prescription regardless of their dosage form and their storage conditions. This should also apply to food-production animals. Exceptions for substances that are considered to be harmful to the organism or containing not desired residues should appear only on a negative list, s. Table 2 EU Regulation 37/2010 and Annex 1b of Regulation on pharmacy-only and non-prescription medicines in Germany.

13. To Section 6 - Articles 72 ff (pharmacovigilance).

The monitoring must be carried out by an independent authority. As a role model we refer to the Paul-Ehrlich-Institute system for the monitoring of adverse reactions to human and veterinary vaccines.

14. Art. 73 para. 2

For clarification, it should be noted that CAM animal practitioners are health professionals in terms of the proposal.

15. Chapter V - Art. 88 ff (Homeopathic medicinal products)

A re-registration as a veterinary medicinal product is dispensable, provided a registration as a medicinal product is already effected in a member State. The additional registration as veterinary medicinal product for each species provides a disproportionate economic burden for pharmaceutical manufacturers. It is to be expected that the availability of homeopathic medicines for the treatment of animals is generally severely restricted and thus the objective of the regulation, i.e. to increase the availability of veterinary medicinal products, will be reversed.

The provisions of § 38 German Medicines Act (AMG) should be transferred into the proposal, according to which there is no need of registration as medicinal product for products placed on the market by pharmaceutical companies, if the production amounts to not more than 1000 packs per year (so-called per 1000 regulation).

Reason:
Homeopathy is part of the world heritage and should therefore also in the field of medical tratment of animals rather be promoted than be restricted. A prescription of homeopathic remedies involves the risk that the knowledge of more than two centuries might fall into oblivion. Prescription for homeopathic veterinary medicinal products limits the use to conventional medicine trained veterinarians and shifts the application of homeopathy from an individual therapy towards standard therapy.

The restriction of the use of homeopathic remedies eliminates the chance of alternative treatment because veterinarians will be more likely comitted to conventional medicine, therefore they will apply naturopathic therapies more often than not according to their allopathic principles .

In homeopathy, mainly potencies far beyond D 6 are used. A homeopathic remedy labelled “D 6” corresponds to a dilution of 1: 1 million. A limitation of homeopathic medicinal products for the use in food-producing animals or animals in general or even prescription lacks any proportionality. The proposal's objective is about the protection of consumers, foode and animal health. Due to their barely detectable drug concentration, homeopathic remedies bear nor risk for consumer health.

To answer risks there might exist concerning the use of homeopathic remedies – if there are any at all, provisions should adopt a so called first safe dilution (concept of “first safe dilution” or “safe only by dilution”), but not introduce prescription or separate/additional registration/authorization as veterinary medicinal products. This should apply to all animals, even to food production annimals.

Thereby, a first but important step would be done in the direction of "Healthy Livestock - healthy products for the consumers", in accordance with the principle of sustainability.

16. Art. 111 ff.

This provision restricts the freedom of therapy of CAM animal practitioners and veterinarians inappropriately. The strict interpretation of the provision to use veterinary medicinal products according to the terms of authorization only, would prevent the application of registered but not authorized homeopahic medicinal products.

s. also Comment No. 67 of the German Bundesrat to Art. 111, BR-Drucksache 420/1/14

Note:

The undersigned organizations represent the professional interests of CAM animal practitioners. The associations are organized as eingetragener Verein under German law. Together, they represent more than 1,700 CAM animal practitioners, the vast majority being women. The Kooperation deutscher Tierheilpraktiker-Verbände includes the following member organizations:

- BKTD - Berufsverband klassischer Tierhomöopathen Deutschlands, professional association of classic animal homeopaths Germany
- DGT - Deutsche Gesellschaft für Tierheilpraktiker und Tierphysiotherapeuten, German Society for animal healers and animal physiotherapists
- DTU - Deutsche Tierheilpraktiker Union, German Tierheilpraktiker Union
- VfT - Verband freier Tierheilpraktiker, Association of Independent Tierheilpraktiker
- VTkH - Verband der Tierheilpraktiker für klassische Homöopathie, Association of Tierheilpraktiker for Classical Homeopathy

The profession of CAM animal practitioner/Tierheilpraktiker is a liberal profession, animal practitioners promote animal health and wellbeing and observe regulations and obligations resulting from the animal welfare act. Experience in complementary and alternative medicine (CAM) and modern medical findings are equally applied for the benefit of animals and their keepers.

Complementary and alternative therapies include in particular homeopathy, traditional chinese medicine (TCM, including acupuncture), phytotherapy, manual therapies, energy methods et al. Regarding the effectiveness of complementary and alternative therapies, there exists extensive research material, s. the data collection under http://www.anme-ngo.eu/de/camineuropa/forschung/datensammlung.html

All members of the signatory organizations and the members of the associations of the Kooperation deutscher Tierheilpraktiker-Verbände have a profound education and training in the field of naturopathy and veterinary basic knowledge and oblige to link modern medical findings with the traditional methods of naturopathy, and the annual training in naturopathic and veterinary subjects.

Regarding the legal situation and importance of the profession of CAM animal practitioners to the Health System s. Dill/Maass, Complementary and Alternative Medicine (CAM) for Animals, http://www.anme-ngo.eu/de/camineuropa/themen/tiere.html.

Economic importance of the activities of CAM animal practitioners

In Germany, there are about 4,500 practicing CAM animal practitioners. The turnover of all practices was estimated for 2013 at about 90 million euros/year. (Source: Prof. Dr. Renate Ear, University of Göttingen, pet study "Economic Factor pet ownership", November 2014, http://www.uni-goettingen.de/de/heimtierstudie-zum-wirtschaftsfaktor-heimtierhaltung/425385.html). These are just figures in the field of pets, without horses and farm animals.