PAN Germany
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Veterinary medicinal products and protection of the environment

Authorisation and use of veterinary medicinal products in the EU-
Legal framework and demands for enhancing the protection of the environment from the adverse effects of veterinary medicinal products

A healty world for all.

Protect humanity and environment from pesticides. Promote alternatives.

Content

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Veterinary medicinal products and protection of the environment

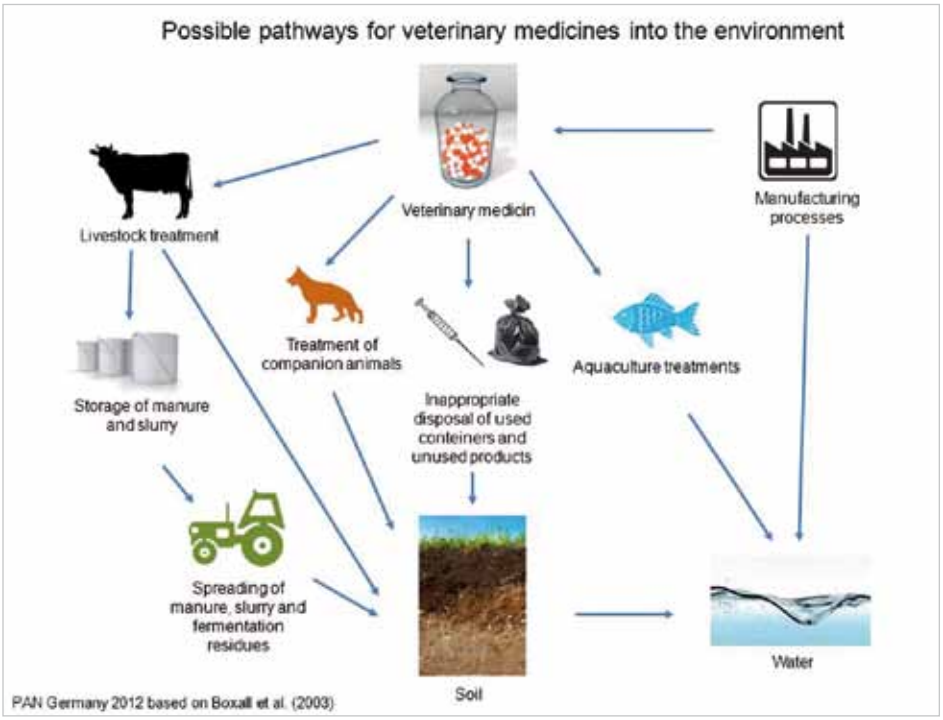
Authorisation and use of veterinary medicinal products in the EU -Legal framework and demands for enhancing the protection of the environment from the adverse effects of veterinary medicinal products

Background and content of this publication

The growing contamination of surface water, soil, and food with residues from veterinary medicinal products has increasingly attracted the attention of policymakers and the general public. It has become apparent that measures are needed on various levels – from pharmaceutical approval, to regulations for use, to technical processes for wastewater treatment – in order to enhance protection of the environment and human health from adverse effects of hazardous pharmaceutical residues. On the backdrop of the current revision of European veterinary medicinal products regulations, this text will present information on the current status of legal regulation in the realm of veterinary medicinal products, the goals of the revision, and the relevant administrative jurisdictions, and will then discuss what improvements are needed from the perspective of precautionary environmental protection.

Adverse environmental effects of veterinary medicinal products

Veterinary medicinal products are intended for use in treating, mitigating, or preventing illnesses or to influence specific body functions in animals. They are used by veterinaries and pet owners as well as by professional livestock holders such as breeders and feedlot operators. Considerable amounts of these medicinal products are released into the environment by intensive fattening operations. These include drugs that target parasites, protozoa, worms, and insects, antibiotics that combat pathogenic bacterial, substances for treating infections, and immunological veterinary pharmaceuticals. These substances enter the environment via animal excrements, livestock manure, waste water, and other farm waste. Medicinal products enter surface water directly as a result of their use in aquacultures. Moreover, the use of so-called pour-on pharmaceuticals to treat grazing animals by pouring liquids directly onto the animals can contribute to the release of veterinary medicinal products into the environment. To date, little is known about how such substances enter the environment through aerosols and dust, but livestock manure is considered to play a significant role in this context.



Many veterinary medicinal products are water-soluble (hydrophilic) as well as persistent. Due to their hydrophilic properties, they are easily disseminated in the environment and are now ubiquitous in flowing bodies of water, soil, and even in groundwater[1]. The adverse environmental impacts of medicinal products have concerned experts for a number of decades[2]. Nonetheless, many questions related to the behaviour of veterinary medicinal products in the environment and their effects on biological communities and ecological systems remain unanswered. The EU also still lacks binding limits for active pharmaceutical ingredients in groundwater and surface water[3]. This deficit is due to a lack of systematic monitoring of veterinary medicinal products and failure to assess the environmental impact of older products that are already on the market. However, recognition that residues of medicinal products in bodies of water are a growing problem is now widely acknowledged. Studies by the German Federal Environmental Protection Agency show that in Germany more than 270 different active pharmaceutical substances (for human and veterinary use) can be found in surface water, sediments, groundwater, and soil; of these, 130 are present in surface water[3]. This last finding is especially alarming, since these pharmaceuticals have effects on the entire aquatic ecosystem. Antibiotics inhibit the growth of plants and primary aquatic producers such as algae and cyanobacteria, antiparasitics affect invertebrates - small animals that that do not develop a vertebral column like insects, worms and crabs -, and hormone residues in bodies of waters have significant effects on the development and reproductive capacities of fish. Other EU member states are also concerned about the negative influence of veterinary medicinal products on the environment. France, for example, has drafted a national plan to combat pharmaceutical residues in water[4]. On a European level, the Framework Directive on Water is now being revised, and environmental NGOs

Although medicinal products today are ubiquitous in flowing bodies of water, soil, and even in groundwater the EU still lacks binding limits for active pharmaceutical ingredients in groundwater and in surface water.

are calling on the EU to add, for the first time, human pharmaceuticals to the list of the so-called priority substances[5]. Priority substances are pollutants of relevance for aquatic ecosystems that are classified as especially problematic due to the hazards they present and the level of residue concentrations of these products measured in bodies of water. For these substances, monitoring procedures, specific quality norms, and emission limits must be defined within the framework of the EU Water Framework Directive (WRRL)[6].

Currently, debate about pharmaceuticals in the environment is mostly limited to expert circles. The situation is quite different with respect to the enormous amounts of antibiotics used in animal farming. Fuelled by concerns about antimicrobial resistance and antibiotic contamination in poultry, public debate is much more intense and policymakers have been called on to define goals for reducing the use of antibiotics. These discussions clearly show that solutions cannot be achieved if stricter regulations are limited, for example, to the sphere of drug regulation. Instead, much broader approaches must be sought that include critical scrutiny of eating habits, production systems, forms of animal husbandry, and livestock fattening regimes.

What laws regulate the market authorisation and use of veterinary medicinal products in the EU?

The approval and use of veterinary medicinal products in the European Union are to a large extent regulated by the following laws:

- European Framework Directive on the Community code relating to veterinary medicinal products (2001/82/EG[7] with changes made by 2004/28/EG[8]) and the
- European Regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Regulation (EG) Nr. 726/2004)[9] including all amending acts to date.

The European Framework Directive 2001/82/EG (in the following referred to as the Directive) regulates the production, placing on the market, labelling, marketing, and use of veterinary pharmaceuticals in the European Union. It includes special provisions for homeopathic veterinary pharmaceuticals, lays down procedures for authorisation, sets standards for labelling and package insert and for monitoring trade with and use of veterinary medicinal products once they have been authorised for the market (pharmacovigilance). The Directive applies to almost all veterinary pharmaceuticals with the exception of medicated feedingstuffs[10]. Annex I of the Directive shows the chemical, pharmaceutical, and analytical standards, requirements for safety and residue testing, and requirements for clinical testing of veterinary medicinal products. Part 6 of Annex I regulates the environmental assessment process. Since 2001, the Directive has undergone numerous adaptations and changes. A consolidated version now means it is possible to retrace all of the revisions realized to date[11].

The European Regulation 726/2004/EG (in the following referred to as the Regulation) sets out in detail how authorisation and supervision of human and veterinary medicinal products are to be implemented with a harmonized procedure for all member states. It includes provisions for the centralised authorisation process (see below) and forms the legal basis for the European Medicines Agency (EMA) established in 1993. Among the responsibilities of the EMA is consultation regarding maximum levels of residues of medicinal products used in animal husbandry and of biocides that are permitted in foodstuffs of animal origin. Since 2004, numerous adaptations and changes to the Regulation have been implemented and added to the original text[12].

What are the core elements of European veterinary medicinal products legislation?

A – Only authorised veterinary medicinal products can be placed on the market

Veterinary medicinal products, like human pharmaceuticals, pesticides, or biocides, are subject to an authorisation process. In the European Union, no veterinary pharmaceutical can be placed on the market without official authorisation[13]. Exceptions from this principle are allowed only in extraordinary cases, for example, when serious animal disease epidemics erupt. Depending on the application process and the veterinary medicinal product involved, the relevant authorising body is the European Medicines Agency (EMA) or the competent national authority in the respective member state. A veterinary medicinal product can only be authorised if it does not have adverse effects on the animal treated, can be readily applied by the veterinary or the owner of the animal, and the benefits are higher than the risks involved in use, including environmental risks. But numerous previously authorised medicinal products that have never been tested for their environmental impact are on the market. Veterinary medicinal products intended for use in animals consumed as human food, whether directly or in the form of products derived from these animals, can only be authorised if regulations governing the maximum residue levels for the relevant active ingredients are in place and the active ingredients are listed in Regulation (EU) Nr. 470/2009 on veterinary medicinal product residues in foodstuffs of animal origin[14].

In the European Union, no veterinary pharmaceutical can be placed on the market without official authorisation. But numerous previously authorised medicinal products that have never been tested for their environmental impact are on the market.

B – Applicants choose between different authorisation procedures

Authorisation of medicinal products in the EU can occur via national, decentralised, or centralised authorisation procedures:

► National Authorisation Procedure
In the national authorisation procedure, applicants seek authorisation in a single member state by submitting to the national authority the relevant documents with proof of pharmaceutical quality, efficacy, and compatibility of the product for the target animal, users, and the environment. The responsible authority assesses the validity of this dossier. If any deficits are determined in the documents, they must be rectified by the applicant within the prescribed period. In Germany, a decision regarding environmental impacts is reached by the Federal Office of Consumer Protection and Food Safety (BVL) in agreement with the Federal Environment Agency (UBA). Since the mid-1990s, national authorisation procedures have increasingly been supplanted by EU procedures. Nonetheless, numerous medicinal products are still on the market that were authorised by a national procedure. Today, national authorisation is generally a first step, which is then followed by a mutual-recognition procedure (see below).

► Decentralised procedure
With the decentralised procedure (DCP), the applicant applies for simultaneous authorisation in more than one EU country of a veterinary medicinal product that has not yet been authorised in any EU country. Here, one member state, the so-called Reference Member State (RMS), takes the lead. After reviewing the validity and completeness of the application, the first authorisation phase begins (duration - 120 days). The RMS first draws up a preliminary assessment report (PAR) and a "list of questions" (LOQ), to which other concerned member states (CMS) can make additions. The RMS evaluates the answers and additions and informs the CMS about the results. This is followed by the second authorisation phase, which lasts 90 days and is similar to the mutual recognition procedure.

► Mutual recognition procedure
In the mutual recognition procedure (MRP), a veterinary medicinal product already authorised in one EU member state is recognized by one or more other member states, as long as no serious grounds for refusing such recognition are found. Mutual recognition can be denied in exceptional cases if potential serious risk to human health, animal health, or the environment is considered to exist. The precise definition of grounds on which mutual recognition can be refused are found in an EU Guideline[15]. The mutual recognition procedure takes 90 days.

► Centralised authorisation procedure
The central authorisation procedure offers applicants a process for acquiring authorisation for a specific medicinal product throughout the EU. Applications are submitted to the EMA and processed by its Committee for Veterinary Medicinal Products (CVMP[16]). National authorisation agencies are also involved in the central procedure, for example as Rapporteur Member States and Co-Rapporteurs. Their dossiers form the foundation for the recommendations of the CVMP. The central procedure is obligatory for some products, in particular for new substances produced with specific biotechnological methods. So-called "innovative medicinal products" that contain new active ingredients and products that represent therapeutic, scientific, or technical innovations or that are of interest throughout the EU can be authorised within the centralised procedure.

C – Reasons for refusing to authorise a product

An application for authorisation of a veterinary medicinal product will be denied when

- ► the potential risks, including environmental risks outweigh the product's benefits,
- ► the therapeutic efficacy is lacking, or
- ► the withdrawal period is insufficient to exclude the possibility of risks for human health due to residues in foodstuffs obtained from the treated animal.

D – Authorisation periods and patent protection

Veterinary medicinal products are authorised for a period of five years. This period can be extended following submission of an appropriate application. If the application for extension is approved, then authorisation generally becomes indefinite. Upon submission of an application for renewal, the summaries of product characteristics (SPC) are also again subject to review. The SPCs are based on the dossier submitted with the original application for authorisation. During the renewal process, new scientific knowledge acquired in the interim must be taken into account, but environmental impacts are considered only to a limited extent. In the course of the reassessment, no new environmental data are collected; instead the benefit-risk-relationship is reassessed. Environmental risks are only addressed if new information about risks has emerged in the interim. Such information – for example, about undesirable environmental effects of pharmaceuticals – theoretically might be generated by systematic pharmacovigilance. However this system in its present design is not suitable to monitor the environmental impact of veterinary pharmaceuticals.

Patents are highly significant economically for the pharmaceuticals industry. Medicinal products authorised by the centralised procedure are protected by patents for a period of ten years. Products authorised through the decentralised procedure or through mutual recognition are protected for eight years. Since revision of pharmaceuticals legislation has begun, the issue of extending patent protection has been discussed; it has been argued that this would "offset" the higher requirements that applicants will have to meet or serve as a stimulus for manufacturers to apply for the authorisation of pharmaceuticals with „minor use".

Many consumers are concerned about the massive use of antimicrobials in intensive livestock farming. Maximum residue levels for veterinary pharmaceuticals in foodstuffs obtained from treated animals are in place. However many consumers consider these regulations to be insufficient. They call for residue-free food and for breeding systems that do not threaten animal health.

How is the environmental impact assessed during the authorisation procedure?

Potentially detrimental effects of veterinary medicinal use on the environment are identified and assessed and measures to reduce risks are established within the framework of the environmental impact assessment. Since 1992, new pharmaceuticals must be subjected to such an assessment. For all veterinary medicinal products that were first authorised before 1992 and for those reviewed before 2005 or authorised as generic products, information on their behaviour in the environment is lacking. For generic pharmaceuticals, environmental impact assessment did not become an obligatory element of the authorisation process until 2004. The so called VICH-guidelines that govern the content and scope of the environmental impact assessment have been in force since 2005.[17] As a result, numerous previously authorised medicinal products are on the market that have never been tested for their environmental impacts and for which current legal requirements do not stipulate that an assessment of environmental effects is necessary. Here, there are considerable deficits and a lack of coherence in current regulations for veterinary medicinal products in comparison to other types of substances.

Assessment of the environmental impacts during the authorisation process is generally conducted in two phases and focuses on the active pharmaceutical ingredients. The first phase is obligatory and involves an assessment of the potential exposure of the environment to the active ingredient. The applicant must provide data on the following aspects:

- target animal species, form of administration, and dosage,
- information on direct and indirect introduction of the active ingredient into environmental systems (e.g. amounts of the active ingredient in excrements), physico-chemical properties, persistence and
- disposal procedures.

If the results of the first phase show that the environment may be exposed to the substance, an impact assessment is carried out in the second phase. The applicant must then provide the authorisation body with data on the active ingredient's behaviour in the environment and its ecotoxicological properties, e.g., its toxicity for earthworms, daphnia, and plants. The VICH-guidelines, which specify the content and extent of the environmental impact assessment, stipulate that a predicted environmental concentration (PEC) of a product of less than 100µg/kg in soil is seen as not posing an environmental risk, so that risk assessment is not obligatory.[18]

Moreover, whether the permissible level of 100µg/kg in soil is sufficient to safeguard the environment from negative impacts from veterinary medicinal products is controversial. A further deficit is the fact that, due to a lack of data, the amounts of veterinary medicinal products in use can only be estimated. There is also a lack of data on the amounts of these substances found in the environment and on the ecotoxicologically relevant concentrations of active ingredients found in farm fertilisers and in the soil. As a result, it is difficult to formulate reliable assessments of how veterinary medicinal products behave in the environment and what their impacts are.

Example: **Deficiencies in the environmental assessment procedure**

Random examination of certain substances previously authorised that had not been previously investigated with respect to their environmental properties revealed that in some cases the threshold value of 100µg/kg in soil was in fact exceeded. If these active ingredients were subjected to an environmental risk analysis within the context of an application for authorisation, they would have to undergo Phase II ecotoxicological review as set out in the guidelines[19]. But this kind of risk assessment has not conducted for products already on the market, even though it is urgently needed from the standpoint of environmental and health policies that follow the precautionary principle.

Why is European legislation on veterinary medicinal products currently being revised?

In revising legislation on veterinary medicinal products, the primary goals pursued by the European Commission are economic, e.g., improving the availability of veterinary medicinal products in the member states, reducing the administrative burden for pharmaceutical companies, strengthening the competitive status of small and medium-sized enterprises (SME), and facilitating trade with veterinary medicinal products in the internal market. In addition, opportunities for improving strategies to combat the spread of microbial resistance to antibiotics are to be assessed.[20] Furthermore, on the backdrop of environmental burdens related to veterinary medicinal products and the increase of antimicrobial resistance and in the interests of preventive environmental protection, PAN Germany's position is that this revision of the legislation in veterinary medicinal products should also enhance the protection of consumers, animal welfare, and the environment.

What is the timetable for the revision of legislation on veterinary medicinal products?

The EU's timetable for the revision process has been spelled out in a "Roadmap"[21]. The first meeting with various stakeholders was held in 2009. This was followed by a public consultation, from April to July 2010, which addressed improvements of the legislative framework and involved various stakeholders, such as state authorisation bodies, pharmaceutical companies, veterinaries, and PAN Germany as the only involved environmental organisation[22, 23]. Following this consultation, the EU Commission invited stakeholders to a meeting in September 2011, at which

Still many questions related to the behaviour of veterinary medicinal products in the environment and their effects on biological communities and ecological systems remain unanswered. Reliable data on the amounts of veterinary medicinal products in use and on veterinary substances found in the environment is lacking. Ecological monitoring for veterinary pharmaceuticals is needed but, so far, not in place.

The revision mainly aims at facilitating trade with veterinary medicinal products in the internal market and at improving market-economic factors. A better protection of the environment has not been one of the main targets of the revision so far. An environmental monitoring program for veterinary pharmaceuticals is not in place.

the need for a central database for authorised veterinary medicinal products was articulated and other issues such as the reduction of the administrative burden and confidentiality and data security concerns were discussed[24]. An expertise prepared for the EU Commission explored deficits in the current legal framework and options for possible revisions and estimated the capacities needed for revision and the costs involved[25]. Besides from conferences organised by involved stakeholders, like the International Federation for Animal Health (IFAH) conference 2011 "Veterinary medicines legislative review – the big debate"[26] and the Chemical Industries Regulations (CIR) conference 2012 "Regulation of Veterinary Medicines"[27], the EU Commission has organised target consultations on pharmacovigilance, marketing authorisation, antimicrobial resistance and small and medium enterprises[28]. There was no specific workshop on veterinary medicinal products in the environment and according to the EU Commission no such workshop is planned. The revision process is now slightly behind schedule. The Commission is currently (end of 2012) drafting its proposal for the revised legislation. It is expected that the Commission will present its draft in the second quarter of 2013. However, proposals that suggest how the revised legislation on veterinary medicines might enhance environmental protection can still be considered. PAN Germany`s impression is that the EU Commission is still "open to ideas". Once the EU Commission's proposal is published, debate and negotiations on the draft will commence in the European Parliament and Council. The goal is to pass the revision – if possible – before the next European Parliament elections are held in 2014.

A brief aside: relationship between legislation on veterinary medicinal products and legislation on pesticides and biocides

In other areas of European regulation, for example on pesticides and biocides, so-called review programmes have been implemented to examine the impacts of substances previously approved for sale. These reviews guarantee that all active ingredients now on the market are assessed by the same standards with respect to their efficacy and potential risks for health and the environment. This process has proven useful in securing harmonisation throughout the EU and in identifying substances that are especially hazardous for human health or the environment, so that they can be removed from the market. No such review procedure is in place for veterinary medicinal products. PAN Germany calls on the EU to ensure that, in keeping with other European product regulations (on pesticides, biocides, chemical substances), decisions on authorising veterinary medicinal products are reached on the basis of the latest scientific knowledge and all active ingredients are reviewed according to most recent scientific evidence.

What institutions are involved in the revision process?

The European Commission's General Directorate Health and Consumers is responsible for animal health and for the revision of legislation on veterinary medicinal products.[29] Also involved is the European Medicines Agency (EMA) with headquarters in London as the decentralized scientific agency of the EU.[30] The national competent authorities of the member states have formed the "Heads of Medicine Agencies" (HMA). The HMA participate in discussions about the revision with their specific expertise and also function as intermediaries in communication between the EU Commission, the European authority EMA, and the governments of the member states. The HMA pay special attention to the impacts of the European procedures and of changes in these procedures on the member states.[31] In order to draw up and present suggestions for the revision, the HMA established a "Task Force Working Group on Improvement of Veterinary Legislation" (TF) in 2008. The task force is composed of representatives of 13 member states, the EMA, and the EU Commission.

PAN Germany's Recommendations

In view of the recognized environmental impacts of veterinary medicinal products, PAN Germany sees an urgent need to revise legislation in the field of veterinary pharmaceutical policies to ensure that the environment and human health will be more effectively protected from the adverse effects of veterinary medicinal products. PAN calls on policymakers to revise existing regulations to meet the following demands.

1. Collect and publish data on commercial use and occurrence of veterinary medicine in the environment

► **The extent, quality, and transparency of data on the use of veterinary medicinal products must be improved.** Precise reports must be made available annually. They should include documentation and publication of data on amounts of products marketed (for domestic use and export), the intensity of use, monitoring of use and trade with veterinary medicinal products, and the introduction of obligatory registration for producers.

► **To document the impact and evaluate possible risk-reduction measures, obligatory environmental monitoring** (surface, ground, and drinking water; soil; sediments) should be introduced.

► **The member states commit themselves to creating public forums** (e.g. on the internet), in which the general public and the most important users of veterinary medicinal products (pet and livestock owners, veterinaries, consultants, etc.) are informed about precautionary measures and non-hazardous alternative procedures.

2. Coherence with other relevant spheres of regulation

► **The goals and provisions of the European veterinary legislation must be in agreement with other European regulations on specific substances, on the environment, on water protection, and on animal welfare.** This should also include a review of problematic veterinary medicinal products to ascertain whether they should be included in the list of priority substances.

► **Establishment of a harmonised, EU-wide legal framework for the use of veterinary medicinal products** with the legally binding goal of reducing the amounts used.

► **Evaluation of the possible introduction of a monograph system for assessing active ingredients** and compiling information on the whereabouts and effects of active substances in the environment

3. Include more environmental protection in the authorization process

► **Introduction of a review programme** for evaluating the environmental effects of veterinary pharmaceuticals that have been approved without being tested for their environmental impacts as well as a regular review of all authorisation decisions based on the current state of scientific knowledge.

► **Supplementary results from independent research on the environmental impacts of veterinary medicinal products** are to be included in the assessment process and during review programmes.

► **Criteria for active ingredients in veterinary medicinal products that are especially hazardous to the environment** must be defined, so that authorisation of such products can be denied in future.

► **The revised legislation should incorporate dynamic risk reduction schemes and the promotion of alternatives** by integrating the substitution principle and implementing comparative assessment during the authorisation process.

► **Authorisation decisions relevant to environmental impacts are to be reached based on state-of-the-art scientific knowledge.** Reduced requirements for data submission (reduction of the administrative burden) cannot be cited as a justification for failing to satisfy this requirement.

4. Promote more conscious handling of animals and responsible use of veterinary medicine

► **The enhancement of preventive measures** and their linkage with questions of animal husbandry must be addressed.

► **Obligatory training for farmers and retailers** about veterinary medicinal products must be introduced. Information on the environmental risks of veterinary pharmaceuticals is to be included in the training program.

► **Those who market and use veterinary medicinal products should be offered comprehensive advice on protection of the environment and health and should be monitored regularly.**

► **Concrete and binding plans for phasing out and substituting problematic products or active ingredients** with fixed, short periods must be prescribed to ensure that substitution occurs in the time period allotted and innovative alternatives are promoted. Special attention is to be paid to alternative processes.

► **Establishing of a legal framework of environmentally sound use of veterinary medicinal products.** This should include a significantly reduced use of antimicrobials and the implementation of integrative, disease prevention measures to protect the health of animal populations (breeding system, housing system, technical measures, cleaning regime, size of stock, etc.). The revised law must stipulate by what date and in what form this framework is to be developed and implemented.

5. Better regulation of the use of antimicrobials

► **Documentation of sales and use of antibiotics must be made mandatory** in EU legislation

► **All data on trade with and use of antibiotics must be made public.**

► **Clear-cut goals for the reduction of the quantities of antibiotics used** in animal husbandry and fatting regimes must be defined.

► **Specific controls and transparent, prompt reporting must be introduced.**

► **Third and fourth generation antibiotics must be banned** from use in animal husbandry.

► **The development of antimicrobial resistance must be considered** in the environmental impact assessment.

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10 The Directive also does not apply to inactivated immunological veterinary medicinal products that are produced on the basis of pathogenic organisms isolated from animals of the same population, to medicinal products prepared by chemists, to veterinary medicinal products based on radioactive isotopes, and to specific additives to animal feed.

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12 www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R0726:20090706:EN:PDF

13 Exceptions are possible under certain circumstances for veterinary medicinal products for aquarium fish, cage birds, homing pigeons, terrarium animals, and small rodent.

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17 Guideline on environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 and 38, passed by Committee for medical products for veterinary use (CVMP) available online at www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004386.pdf. VICH refers to the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products, a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration.

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26 www.ifaheurope.org/EventDetails.aspx?ID=96&SubMenuId=26&MenuId=4

27 www.informa-ls.com/event/vetmed12/highlights#bullet12000377-0

28 At the time this document was finalized, the minutes of these meetings had not yet been published.

29 www.ec.europa.eu/health/veterinary-use/rev_frame_index_en.htm

30 www.emea.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000235.jsp&mid=

31 www.hma.eu/271.html

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PAN Germany is a charitable organisation which provides information on the adverse effects of pesticides and promotes environmentally friendly and socially just alternatives. We are part of the Pesticide Action Network International. Our work areas range from critical assessments of the pesticide industry to constructive interaction with policy-makers to practical services for farmers and consumers.

A healthy world for all. Protect humanity and environment from pesticides. Promote alternatives