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EUFEPS-Publication

Position Paper: EUFEPS Network on Veterinary Medicines Initiative: An interdisciplinary forum to support Veterinary Pharmacology and promote the development of new pharmaceuticals for Animal Health

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Abstract

Veterinary medicines account for a substantial portion of the production, sale, and consumption of medicines in Europe, and probably world-wide. This calls our attention to the fact that only healthy farm animals can ensure safe and sufficient livestock products to meet the growing demand for animal protein. Human and veterinary medicine share many common features - expressed and symbolised by the “One Health Concept”. This concept forms the logical basis for the maintenance of healthy livestock by the control of zoonoses and foodborne diseases, the prevention of poor sanitary conditions, and the reduction of microbial and parasitic threats, including resistance to antibiotics and anti-parasitic drugs. Achieving these aims will require international cooperation and interdisciplinary action. A new initiative of the European Federation for Pharmaceutical Sciences (EUFEPS) – the Network on Veterinary Medicines – has the potential to manage and overcome these challenges.

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1. Veterinary medicines and the “One Health” concept

1.1. Background

Veterinary medicines are a considerable part of the total production and use of medicines world-wide. The wide recognition of the concept of “One Health” symbolises the many shared aspects of human and animal health. Zoonoses, foodborne diseases, poor sanitary conditions, microbial threats, and resistance to antibiotics or anti-parasitic drugs (with the likely consequence of their spread into the environment) are well-documented as major challenges shared by both medical disciplines. The “One health” concept is impressively substantiated by the fact that 60% of human infectious diseases evolve from animal pathogens and that 75% of emerging human infectious diseases have an animal disease origin (OIE, 2015a).

The validity of the “One Health” concept is also supported by the mutual use of many pharmaceutical substances (or at least identical classes of pharmaceuticals) both in veterinary and human medicine. For example, Table 1 shows a number of antimicrobial substances used in animals and in human patients. Among the shared antimicrobial substances are 3rd/4th generation cephalosporins, fluoroquinolones and macrolides. These are classified by the WHO as critically important for human medicine (WHO, 2011a) and appear to also be important for the treatment of a variety of animal diseases (OIE, 2015b).

The latest Nobel Prize in Medicine was awarded to the scientists developing the animal antiparasitic drugs of the avermectin series, which were, much later, used to treat crippling parasitic diseases among major human populations in Africa, primarily Elephantiasis and River blindness (Campbell, 1991).

Only food derived from healthy animals can ensure safe and sufficient livestock products and help to combat malnutrition. Furthermore, the worldwide demand for animal protein is estimated to increase by 70% between now and 2050 (FAO, 2015). Presently, animal diseases are expected to reduce global production of food animals by more than 20% (Vallat, 2015). International cooperation and interdisciplinary action are required to sustain healthy livestock for safe and sufficient food production, to support animal and human health, and to safeguard the environment. Safe and effective pharmaceuticals and their prudent use are indispensable tools in approaching and achieving these objectives (FAO, 2015).

A new initiative – the EUFEPS Network on Veterinary Medicines - has the potential to cope with these challenges. It will be instrumental in inviting and stimulating faculties and students to meaningful European collaboration, including the creation of research programmes and applications for European grants. Contacts with the relevant European regulatory bodies (e.g., EMA, EFSA, ECDC, and others), as well as with sectors of academia and industry involved in research and development of innovative medicines and delivery systems appear crucial for these Network activities.

2. Why the European Federation for Pharmaceutical Sciences is a suitable platform to support a Veterinary Medicines Network

The European Federation for Pharmaceutical Sciences (EUFEPS) is a non-partisan organisation representing national and other organisations and individuals with significant interests and expertise in pharmaceutical sciences and regulations. A number of EUFEPS expertise networks are already established, some of which may be instrumental in broadening and deepening the activities of the Network on Veterinary Medicines. These include the Network on Systems Pharmacology (currently being formed), the European Network on Pharmacogenomics Research and Implementation (EPRIN), as well as the Network on Bioavailability and Biopharmaceutics (Table 2). Additionally, the EUFEPS Networks on Safety Sciences, on Environment and Pharmaceuticals and on NanoMedicine as well as on Regulatory Science are promising additional partners for cooperation. This is especially true as so many new technologies are entering the area of veterinary medicinal products (VMPs) and require significant scientific input if their potential benefit-risk profiles are to be thoroughly evaluated.

The EUFEPS was created 25 years ago by more than 20 national pharmaceutical science societies and faculty members to make
pharmaceutical research more impactful. In fact, EUFEPS’ scientific activities are driven mostly by networks and their steering committees, which also efficiently cover the changing regulatory environment, especially for the human and also for the veterinary pharmaceutical industry.

EUFEPS has resources to manage the practicalities of supporting its activities as outlined above, and to arrange the necessary meetings and conferences. The purpose of a Network on Veterinary Medicines is not, primarily, to help to fulfill the goals of EUFEPS. Rather, its commitment is to address and have an impact on the solution of ongoing issues in veterinary medicine. Scientists involved in VMPs, such as regulatory assessors, pharmacologists, and formulation scientists working for the veterinary pharmaceutical industry, as well as veterinary clinical experts, should therefore see it as useful to promote EUFEPS’ basic principle: “advancing sciences for better medicines and health”.

3. Some specifics of veterinary medicines

In the EU and worldwide, VMPs cannot be placed on the market without prior authorization. The marketing of VMPs is regulated by the rules established in Regulation (EC) No 726/2004 and Directive 2001/82/EC (as amended by Directive 2009/9/EC). The procedures for obtaining a marketing authorization for VMPs are similar to the legislative requirements for human medicinal products, but with the addition of specific requirements, e.g., referring to pharmaceutical formulation, consumer safety, and environmental safety.

3.1. Pharmaceutical formulations

Due to the diverging requirements and manifold options for the treatment of different animal species, often kept in distinct livestock farming systems (and frequently in large numbers), VMPs need to be produced in formulations that are sometimes uncommon for human medicinal products. Innovative administration routes for VMPs are often paramount and not limited to oral use (e.g., tablets, powders) and intravenous injections. Subcutaneous as well as intramuscular injections are highly common for VMPs, but special administration routes require specific pharmaceutical sciences: intramammary formulations, but also water soluble formulations for application via drinking water, (transdermal) spot-on formulations, feed medications, intraruminal, intratrauternal, long-acting formulations, and high-pressure percutaneous formulations are widely used for the effective and safe administration of VMPs. In fact, veterinary formulations may sometimes be the precursors of use in humans. As the requirements for the quality of VMPs and human medicinal products are essentially similar, and both follow the rules of Good Manufacturing Practice, EUFEPS, with its competence in pharmaceutical sciences, may contribute significantly to the successful development of new, innovative VMP formulations and can provide an excellent platform for all involved in this issue.

3.2. Consumer safety

VMP legislation differs between products intended for use in domestic animals (e.g., dogs, cats) and those used in treatment of food producing species such as ruminants, pigs, horses, poultry and fish. This distinction accounts for the fact that administration of a VMP to food producing animals may result in the presence of residues in foodstuffs obtained from these animals. Such residues, be they active ingredients, excipients, degradation products formed during storage of the drug, or metabolites formed in treated animals, might remain in animal derived food commodities and compromise the health of the consumer.

Therefore, VMPs intended for treatment of food producing animals may only contain pharmaceutically active substances for which maximum residue limits (MRLs) have been set. The obligatory establishment of MRLs in foodstuffs of animal origin is laid down in Regulation (EC) No 470/2009. Substances for which no safe MRLs can be fixed are inserted into Table 2 of Commission Regulation (EU) No 37/2010 and are explicitly forbidden for use in food producing animals.

Regulatory authorities are working on procedures to extrapolate such MRLs to other tissues and species where possible, as the obligatory setting of MRLs is the most limiting legislation having a direct consequence for the availability of VMPs for “minor species” (e.g., goats, dairy sheep, rabbits), where the development of specific data is too costly to justify the investment. For (potentially) food producing horses, next to the substances listed in Table 1 of Commission Regulation (EU) No 37/2010, additional therapeutics are allowed according to Commission Regulation (EU) No 122/2013 with a withdrawal period of six months. Experts of the EUFEPS may significantly contribute to generating and evaluating data on food safety related to the use of VMPs, which will increase both consumer safety and animal welfare.

3.3. Environmental safety

According to Directive 2001/82/EC, amended by Directive 2004/28/EC, an environmental risk assessment is mandatory in any application for marketing authorizations for a veterinary medicinal product. Guidance documents (EMA, 2000; EMA, 2005; EMA, 2009) regulate the 2-tiered assessment of the possible risks to the environment that may be caused by the use of the product: in Phase I the extent of environmental exposure is evaluated with regard to target species, mass use vs. individual treatments, administration pattern, excretory behaviour, etc.

If certain threshold values of calculated concentrations in soil (predicted environmental concentration, PECsoil) or water (environmental introduction concentrations, EICaquatic) are not exceeded, the assessment is completed in Phase I. If these trigger parameters are violated, Phase II is opened. It considers the physico-chemical, pharmacological, and toxicological characteristics of the product, including decomposition behaviour and effects on certain aquatic organisms (e.g., algae, aquatic invertebrates) in more detail.

The potential ecotoxic effects of a veterinary medicine are subject to a combination of parameters, including amount used, usage pattern, route of administration, metabolism, degradation during storage, persistence in soil and water, toxicity to terrestrial and aquatic organisms, and bioaccumulation potential (Boxall et al., 2002).

Both broad spectrum endectocides of the macrocyclic lactone group and antimicrobials belong to groups of veterinary medicinal products presently causing the most environmental concern. EUFEPS has already established a Network on Environment and Pharmaceuticals and, therefore, can offer expertise in the field of environmental safety of pharmaceutical substances and their metabolites on aquatic and/or terrestrial organisms (Table 2).

4. Goals and mission of the Network on Veterinary Medicines initiative

In addition to legislation issues, development of new drug substances and delivery systems for animal health, availability, and clinical use of VMPs (which include immunological products and vaccines), the initiative will prioritize the academic teaching and training of young veterinary professionals and formulators for veterinary drug delivery.

In pursuing these objectives, the initiative would benefit from collaborating with some of the already existing EUFEPS networks, in addition to cooperating with academia, industry, and with governmental and regulatory institutions. National and international healthcare bodies and organisations dedicated to the teaching and training of young scientists in the pharmaceutical and veterinary sciences are also potential key partners. Objectives could be achieved by:

• Increasing interactions between experts from pharmaceutical and veterinary sciences, thus identifying issues where scientists from academia, industry, and regulatory agencies can work together;
• Promoting interdisciplinary exchange of experience and knowledge among human medical, veterinary medical, and pharmaceutical disciplines, using the network to form research consortia;
• Strengthening academic research to promote the emergence of new concepts, principles and mechanisms of action to develop innovative new VMPs and medicinal products;
• Supporting the development of academic research in the fields of veterinary and pharmaceutical sciences with regard to VMP development, pharmacology, toxicology, and innovative delivery systems. Some veterinary universities are perhaps too small to develop their own research and PhD programmes;
• Supporting the education and training of future healthcare professionals (in veterinary practice, pharmacy, and industrial research, including continuing professional development), and to initiate/promote research in Pharmaceutical Sciences;
• Concentrating efforts to replenish the arsenal of medicines intended for use in animals to address the shortage of available therapeutics for minor use and/or minor species;
• Encouraging the European Commission to initiate calls for research in the area of veterinary medicines, such as Horizon 2020; once these calls are in place, form strong consortia to apply for funding (IMI, EU-funding).

5. Scope and tasks

The scope of the Network on Veterinary Medicine initiative is linked to the extensive range of veterinary and pharmaceutical sciences, including the vast range of responsibilities of the veterinary and pharmacy professions in research, education of students, public health, industry, academia, and governmental institutions but also in practice. A core competency of the envisaged network is to address issues related to the availability of safe VMPs with potentially superior efficacy. The focus is also on their possible concurrent or intended use in human medicine.

A central field of interest is the safety of VMPs, including the protection of users (e.g., veterinary surgeons, farmers), drug tolerance in target animals, and environmental tolerance. Additionally, the fate of the various ingredients in VMPs (including metabolites formed in animals and excreted via urine or faeces and their persistence and biological activity in the environment) has attracted major scientific interest. For instance, the presence of human as well as veterinary antibiotics in soil and water, and their potential roles in promoting resistance in bacteria, has become a matter of great interest (Kümmerer, 2003; Xi et al., 2009).

The use of steroids or steroid–like agents (or any other substances that promote the growth of animals with hormone–like actions) is strictly prohibited in the European Union (EU). Council Directive No 96/22/EC, as amended by Directive No 2008/97/EC, states that residues of certain substances with thyrostatic, oestrogenic, androgenic or gestagenic activity may be dangerous for consumers and may also affect the quality of foodstuffs of animal origin.

As “traditional” growth-promoting substances are probably still being developed and misused, more recent genetic technologies (i.e., “gene doping”) have appeared on the horizon and become a realistic, although illegal “performance enhancing” option. “Gene doping” approaches may constitute an attractive option for i) animal husbandry for food production and ii) animal performance, particularly with regard to sports. Controlling both the illegal use of growth promoting substances and the manipulation of genes requires an adequate knowledge of veterinary drug legislation and animal protection laws as well as the international standards, guidelines, and rules that apply to sport animals. Such control should be exercised with the cooperation and support of the official bodies regulating and controlling the marketing and use of VMPs, and/or international anti-doping organisations. Scientifically, advanced technologies including analysis of metabolomics and proteomics, drug residue monitoring and screening techniques are also necessary. Additional in silico/mathematical model-based approaches might complete the spectrum of investigation methods required to address doping (Mochel et al., 2013).

All of these objectives can best be achieved with the help of a capable and specialised network that is explicitly dedicated to solving problems related to veterinary medicines.

5.1. Development of new medicines and/or principles for targeting animal diseases

There are a number of veterinary drug therapy problems currently awaiting solutions. As mentioned above, some of these are strongly linked to human medicine. Due to the variety of animal species and indications to be taken into consideration, the range of issues related to the use of veterinary medicines is broad and heterogeneous. Among the most urgent problems is the global emergence and spread of antibiotic resistance, which carries the potential for future ineffectiveness of antimicrobial treatments in veterinary and human medicine. The phenomenon of co- and cross-resistance, and the ability to transfer resistance from one species of bacteria to another (e.g., horizontal resistance transfer from commensal bacteria to human pathogens), makes the situation even more problematic. A prominent example is Methicillin-resistant Staphylococcus aureus infections, whether they are hospital-, community-, or livestock-acquired.

It is worth mentioning that, according to recently reported sales data on antimicrobial agents in 26 EU/EEA countries, antimicrobial substances for use in food producing animals amounted to 7982.0 tons in 2012, clearly exceeding total use in humans, which amounted to 3399.8 tons (ECDC, European Centre for Disease Prevention and Control et al., 2015).

Novel antibiotics for use in veterinary medicine will not be available in the near future and new pharmacological approaches to combat bacterial infections must therefore be considered. This applies not only to the prophylactic, metaphylactic, or therapeutic management of bacterial or viral infections in individual animals or whole flocks but also to VMPs indicated, as mentioned above, for so called “minor use in minor animal species” such as sheep, goats, fish, farmed deer, and even honey bees (EMA, 2014). Due to the small size of this market, the spectrum of available pharmaceuticals is limited and not accompanied by adequate commercial return on investment.

In addition to the problem of antibiotic resistance, resistance to anthelmintic drugs is emerging. The excessive and irrational use of anthelmintic drugs has resulted in resistant nematodes; today there are reports about resistance to all drug classes available on the market, i.e., benzimidazoles, tetrahydropyrimidines and macrocyclic lactones (Kaplan and Vidyashankar, 2012). In many parts of the world, even multiple-resistant parasites are prevalent (Cezar et al., 2010). Since the introduction of ivermectin (one of the macrocyclic lactones) in 1981, no novel anthelmintic drug classes has been developed for use in livestock or horses, with the exception of monopantel in New Zealand. The emergence of anthelmintic resistance is a problem for both animal and human health. In addition, more knowledge of the pharmacological features of anthelmintics is required to optimize pharmacological activity and to achieve sustainable use.

However, there are also pharmacotherapeutic gaps related to the treatment of “major food animal species” such as cattle, sheep, pigs, chicken, and salmon. For reasons of consumer protection, a number of pharmacological substances had to be withdrawn from the market without being replaced by new authorized compounds. A compelling example is the recent ban on nitroimidazoles and nitrofurans, which left no therapeutic option for the treatment of the protozoan infection of turkeys with Histomonas meleagridis (which causes blackhead disease) or of cows infected with Trichomonas foetus and showing clinical signs of infertility.
In general, expertise concerning the pharmacokinetic and pharmacodynamic properties of available therapeutic substances - embedded in the clinical contexts in which they are applied - contributes to both animal welfare (efficacy of VMPs used in practice) and public health (food safety). The most recent developments in these areas have helped to optimise both the selection (and formulations) of VMPs in specific cases as well as the applied dosage regimens.

There are additional unanswered questions related to drug treatment in veterinary medicine. Examples are the lack of or deficits in advanced techniques to model and simulate drug disposition kinetics in different animal species, and the continued lack of alternatives to classical antibiotics (alternative substances/prophylactic approaches) in view of the increasing microbial resistance problem. There are related problems with certain antiparasitics (e.g., anthelmintic resistance). There are many unresolved pharmacotherapeutic issues in veterinary medicine. Their number and heterogeneous characteristics exceed the scope of this paper. They include the lack of eye medications, cytostatic agents (for dogs and cats), antiparasitics (e.g., against ticks (for cats)), vaccines and immunological products (e.g., against emerging diseases such as Middle East Respiratory Syndrome). Further regulatory and scientific challenges relate to novel methods of treatment such as stem cell therapy, antiviral therapy, and individualized treatment options.

5.2. Regulatory issues/legal aspects

Regulatory issues are among the core competencies of the EUFEPS networks. Essential elements of the complex legal framework governing medicinal products in the European Union are presently being revised; among these is, for instance, Regulation (EC) No 726/2004, which sets community procedures for the authorisation and supervision of medicinal products for human and veterinary use. Additionally, work is currently in progress on a draft of a novel Regulation of the European Parliament and of the Council on Veterinary Medicinal Products (European Commission, 2014). The objectives of revising the current legislation on VMPs are as follows:

- Increase the availability of VMPs;
- Reduce the administrative burden;
- Stimulate competitiveness and innovation;
- Improve functioning of the internal market;
- Address veterinary and public health issues related to antimicrobial resistance.

Additional areas of interest for the Network on Veterinary Medicines may include drug categories without any legal community prescriptions, e.g., those related to the production and use of autogenous (herd-specific) vaccines or medical products for veterinary use. A recent study revealed an extreme heterogeneity among national legislations for herd-specific vaccines in European countries. Despite the importance of this class of vaccines, an international harmonisation of the terminology, as well as international production standards, are currently missing (Attia et al., 2013).

In addition, issues related to generic VMPs have been discussed in the past. Although the marketing of such products can be expected to increase competition, leading to price cutting and enhanced availability, it has been argued that the characteristics of generics may differ from those of the original product, e.g., with respect to pharmaceutical equivalence and clinical efficacy (Junquera, 2015; Toutain and Bousquet-Melou, 2013).

5.3. Academic graduate and postgraduate training

The identification and fostering of appropriate teaching techniques are essential to raising awareness of and increasing interest in pharmacological, toxicological, and safety sciences and public health issues related to the use of VMPs, such as the prudent use of antibiotics and antiparasitics in the veterinary community. This also includes new developments of current regulations both at the national and the community levels, and improvements related to the practice of veterinary medicine through:

- Interactions among scientists and lecturers working in academia or related institutions to support the understanding of i) the requirements of VMPs, including their optimal use; and ii) the potential benefits of pharmaceutically feasible achievements;
- Development of innovative products for veterinary medicines;
- Management of veterinary pharmacies;
- Storage and transport of drugs in veterinary vehicles;
- Importance of pharmacovigilance;
- Environmental safety.

Both students and professionals in veterinary medicine should be offered a thorough pharmacological training in “classical” pharmacology, which is rarely included in the standard university curriculum. Topics of significance include numerous areas of pharmacology and may

### Table 1

| Class of antimicrobial substance* | Food producing animal species |
|----------------------------------|------------------------------|
| Sulphonamide                     | All                          |
| Diamino-pyrimidin-derivate (trimethoprim) | All                          |
| Penicillins                      | All                          |
| Cephalosporins                   | All                          |
| Quinolones and fluoroquinolones  | All (target species varies with substance) |
| Macrolides                       | All                          |
| Phenicols (Florfenicol)          | All                          |
| Tetracyclines                    | All                          |
| Pleuromutilins                   | rabbits, pigs, chickens, turkeys |
| Lincosamides                     | All                          |
| Aminoglycosides                  | All                          |
| Ansamycin (Biflaximin)           | cattle                       |
| Polypeptides (Colistin)          | All                          |
| Beta-lactamase inhibitors (clavulanic acid) | cattle, pigs |

* This list is based on Commission Regulation (EU) No 37/2010 and notes only antimicrobial classes and compounds. VMPs are authorized for designated species (target species) and may contain only substances for which maximum residue limits (MRLs) have been fixed for edible tissues and/or products of this species (Table 1 of the Regulation). The table shown here is not exhaustive. Full information on individual substances, target species, MRLs of target tissues (muscle, fat, liver, kidney) or products (milk, egg, honey), and other provisions are provided in the Regulation mentioned [as amended]. The spectrum of VMPs containing substances of these classes may vary between EU member states (Schmerold and Ungemach, 2004).
pharmaceutical industry or within regulatory bodies in veterinary graduates are ideal candidates for positions available in the veterinary medicinal products all fall under the scope of the EUFEPS Network.

This Network offers academic, industrial, and regulatory professionals in the various scientific fields a platform focusing on research and how to best apply findings and learning in practice. This includes collaborative contributions to personalised medicines – by promoting pharmacogenetic/genomic knowledge and expertise in establishing clinical evidence for safe and effective medicines and treatments using medication, based on a patient's genetic or other predisposition.

This Network powers science-based process understanding and quality-by-design for medicines. It also contributes to education and training in the field and fosters hands-on implementation of systems approaches and emerging technologies in pharmaceutical production processes.

This Network is dedicated to the development of safety sciences for medicines. It has organised several workshops focusing on education and training for safety scientists. The European Innovative Medicines Initiative (IMI) education and training project on safety sciences stems from this Network and is still on-going.

6. Synopsis

Development of innovative medicines “to meet unmet needs” in veterinary medicine, participation in the revision of the current regulatory framework, and advanced training of scientists working in research and development of VMPIs all fall under the scope of the EUFEPS Network on Veterinary Medicines initiative. The success of this initiative will depend on the engagement and expertise of cooperating specialists and is likely to benefit from the experience and means of other EUFEPS networks.

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