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Network on veterinary medicines initiated by the European Federation For Pharmaceutical Sciences

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The European Federation for Pharmaceutical Sciences (EUFEPS) was founded 25 years ago by more than 20 national pharmaceutical societies and faculty members. As a pan-European organization, it brings together pharmaceutical societies as well as academic, industrial and regulatory scientists engaged in drug research and development, drug regulation and education of professionals working in these fields. EUFEPS represents pharmaceutical sciences in Europe and is recognized as such by both the European Commission and the European Medicines Agency. EUFEPS cooperates with the European Federation of Pharmaceutical Industries and other European organizations and maintains global connections with agencies such as the US Food and Drug Administration and the American Association of Pharmaceutical Scientists. EUFEPS has established specified networks forming the basis of its activities. The creation of a Network on Veterinary Medicines is prompted by the manifold problems resulting from the use of veterinary drugs and its inherent interconnections with human medicine, environmental and public health. A long-term goal of this initiative was to expand the spectrum of available therapeutics for use in animals, including the development of innovative delivery systems.

1 | INTRODUCTION

There are currently many national or international organizations and societies devoted to promoting veterinary sciences as a whole. These include the World Organization for Animal Health (OIE), the Global Animal Medicines Association (Health for Animals), the World Veterinary Organisation, the World Small Animal Veterinary Association (WSAVA), the World Association for Advancement of Veterinary Parasitology (WAAVP) and the European Board of Veterinary Specialisation (EBVS) as well as the European College of Veterinary Pharmacology and Toxicology (ECVPT). A key prerogative of these organizations is to contribute towards improved animal health and animal welfare in conjunction with efforts to address various issues related to animal diseases and public health. In this publication, we report on a new Network of the European Federation for Pharmaceutical Sciences (EUFEPS) specifically focusing on all

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scientific aspects of veterinary pharmaceuticals related to preclinical research, pharmaceutical quality, clinical use, legislation and regulatory policy as well as education and academic training (Dencker et al., 2016).

2 | THE EUROPEAN FEDERATION FOR PHARMACEUTICAL SCIENCES (EUFEPS)

EUFEPS is a pan-European organization founded 25 years ago by more than 20 national pharmaceutical societies and faculty members. It combines pharmaceutical societies and scientists engaged in drug research and development, drug regulation, policymaking and education of professionals in the field. As an independent organization, it constitutes a platform to enable interdisciplinary collaborations that will lead to safe, effective, innovative, economic and timely medicines (EUFEPS, 2016).

The European Commission recognizes EUFEPS as an integrative body representing pharmaceutical sciences within Europe. Additionally, the European Medicines Agency (EMA) acknowledges EUFEPS as a neutral scientific resource providing independent opinions on draft regulatory guidelines. EUFEPS works with other European organizations, such as the European Federation of Pharmaceutical Industries and Associations (EFPIA), to help identifying industrial needs and promoting education in the field of pharmaceutical sciences. Other initiatives include the New Safe Medicines Faster project proposed at the EU 6th RTD Framework Programme for Research and Technological Development (Bjerrum & Linden, 2011). Bringing together European scientists from all disciplines within the pharmaceutical sciences is a main goal of EUFEPS.

EUFEPS plays an active role in all international discussions that relate to pharmaceutical sciences across the globe. It is recognized as a key stakeholder by the US Food and Drug Administration (FDA), and it works actively with its sister organization, the American Association of Pharmaceutical Scientists (AAPS). Additionally, EUFEPS collaborates with the International Pharmaceutical Federation (FIP) and maintains close ties with many other international organizations in the field of pharmaceutical sciences (EUFEPS, 2016).

TABLE 1 Present EUFEPS Networks[a]. All Networks inherently constitute a positive setting for research, development and evaluation of veterinary pharmaceuticals

Network	Scope and aim
Bioavailability and biopharmaceutics	Biopharmaceutics form the bedrock of many of the activities of the societies contributing to the EUFEPS ("Member Societies"). The activities of this network have provided important opportunities to assist the legislature in defining a harmonized approach across Europe (e.g., bioavailability and bioequivalence guidelines). Efforts focus on scientific questions which arise from poorly understood areas.
PharmacoGenomics research and implementation	This Network provides a platform focusing on research and how to best apply findings and learning in practice. This includes collaborative contributions to personalized medicines or precision medicine 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.
Environment and pharmaceuticals	This Network addresses scientific achievements and discusses various issues related to pharmaceutical exposure in the environment, including attempts towards global harmonization.
Nanomedicine	This Network focuses on pharmaceutical and biomedical sciences and the diagnostic and therapeutic aspects of nanomedicine, primarily in cooperation with related nanotechnology fields.
Quality-by-Design (QbD) and process analytical technology (PAT) sciences	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.
Regulatory science	This Network offers academic, industrial and regulatory professionals in the various scientific fields brainstorming meetings, workshops and discussions on strategic goals and key issues in translational research covered by the pharmaceutical sciences.
Safety sciences	This Network is dedicated to the development of safety sciences for medicines. It has organized 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 ongoing.

[a]Their common aims lie in the promotion of scientific collaboration, cooperation and coordination, support of joint activities and engagement in education and training. Thus, forums for academic, industrial and regulatory professionals in respective scientific fields have been developed. Systems Pharmacology is an emerging new Network, as is the one proposed in this article—Veterinary Medicines (quoted from Dencker et al. (2016)). Reprinted from European Journal of Pharmaceutical Sciences 91, L. Dencker, K. Hellmann, J. Mochel, S. Şenel, E. Tyden, J.C. Vendrig, H. Linden, I. Schmerold, 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, I–VII, Copyright (2016), with permission from Elsevier.

2.1 | EUFEPS Networks

EUFEPS Networks and their steering committees primarily move EUFEPS scientific activities forward. Already established EUFEPS Networks include the Networks on Safety Sciences, Environment and Pharmaceuticals, NanoMedicine, Regulatory Science, PharmacoGenomics Research and Implementation (EPRIN), Bioavailability and Biopharmaceutics, and Systems Pharmacology (Table 1).

Through the establishment of a new Network on Veterinary Medicines, EUFEPS expands its array of existing Networks and its relevance in the area of veterinary pharmaceutical sciences. All EUFEPS Networks have the potential to be partners for future collaboration with the Network on Veterinary Medicines.

EUFEPS Networks could therefore significantly help solve many problems related to the availability and clinical use of therapeutics for farm and pet animals, such as antimicrobials and antiparasitic substances, and new drug administration forms, including the evaluation of user safety and potential ecologic effects. Moreover, the scientific background and experience of EUFEPS could be valuable for the assessment of ongoing regulatory issues and legal aspects, graduate and postgraduate education and training (Table 2).

3 | ONGOING ISSUES RELATED TO VETERINARY MEDICINES

In line with the "One Health" principle, a strong connection between human and veterinary medicine is essential. The Network on Veterinary Medicines within the EUFEPS framework will contribute to this objective in the future. In fact, many of the present or emerging problems and prospects of veterinary medicine are best initiated using the instruments of multidisciplinary communication and cooperation. Several "One Health" foci are summarized in Table 3. Virtually, all of these issues overlap with the activities of established EUFEPS Networks.

3.1 | Objects of the Network on Veterinary Medicines in summary

A long-term goal of the veterinary network is to leverage the various sets of expertise offered by the EUFEPS to expand the spectrum of therapeutics intended for use in animals, including immunological products, vaccines, novel therapies or innovative drug delivery systems.

The objectives of the veterinary network can be summarized as follows:

- Strengthening interactions between human, pharmaceutical and veterinary sciences, thus fostering interdisciplinary exchanges of expertise between these disciplines;
- Strengthening academic research in related disciplines to promote the emergence of new concepts, principles and mechanisms of action to develop innovative Veterinary Medicinal Products (VMPs);
- Supporting the development of academic research and collaboration in the fields of veterinary and pharmaceutical sciences with particular regard to more efficient, safe and innovative VMPs. All veterinary and pharmacy faculties, as well as other related disciplines, are expected to benefit from such network activities;
- Scientifically advancing technologies including *in silico*/mathematical approaches involved in the analysis of metabolomics and

TABLE 2 Conceivable scientific exchange of the Network on Veterinary Medicines with established EUFEPS Networks

Relevant issues of the Network for Veterinary Medicines	Suitable Networks for joint activities
Strengthening interactions between medical, pharmaceutical and veterinary sciences	Quality-by-Design (QbD) and Process analytical technology (PAT) sciences Regulatory science Safety sciences
Strengthening academic research (new concepts, principles and mechanisms of action); development of innovative new VMPs including innovative delivery systems	Nanomedicine Pharmacogenomics research and implementation
Novel individualized medication; legal (and illegal) use of pharmaceuticals (including growth-promoting compounds)	Pharmacogenomics research and implementation Regulatory science Safety sciences
Analysis of metabolomics and proteomics, veterinary drug residue monitoring	Safety sciences Bioavailability and biopharmaceutics
Ecotoxicity of VMPs (fate and biological activity of the VMP ingredients and metabolites excreted via urine or faeces in the environment)	Environment and pharmaceuticals
Veterinary drug regulatory processes (assessment, authorization, supervision of VMPs); strategy discussion, science policy	Regulatory science
Education and training of health care professionals in veterinary practice, pharmacy or industrial research	All EUFEPS Networks

TABLE 3 Continuing issues related to Veterinary Medicine

Thematic area	Case example	Remarks	Problem	Reference
One health paradigm	Common use of pharmaceutical substances in human and veterinary medicine	All classes of antibacterial substances used in veterinary medicine are also registered for use in human medicine	Third- and fourth-generation cephalosporins, quinolones, macrolides and polymyxins have been categorized as "Highest Priority Critically Important Antimicrobials" for Human Use by the WHO	WHO (2017)
Public health Environment	Only food derived from healthy animals can ensure safe and edible livestock products	Animal diseases are expected to reduce global production of food animals by more than 20%	Spread of (zoonotic) bacteria conveying antimicrobial resistance genes, drug residues in animal edible tissues and products, or the presence of veterinary antibiotics in soil and water	Vallat (2015); EFSA and ECDC (2017); Kümmerer (2003); Xi. et al. (2009)
Development of new therapeutic strategies	The global emergence and spread of antimicrobial resistance are a threat to effective prevention and treatment of infectious diseases	Sales data from 26 EU/EEA countries in 2012 amount to 7982.0 tons of antimicrobials used in food-producing animals; this is twice the amount of antibiotics reported for human medicine	New pharmacological, biological or alternative approaches are needed to reduce the overall use of antibacterials in animals	ECDC, EFSA, EMA (2015); EMA (2014, 2016)
	Parasitic helminths become increasingly insensitive to a wide array of anthelmintic drugs	Since the introduction of ivermectin in 1981, no novel anthelmintic drug class has been developed for use in livestock or horses, except for monepantel	Widespread antiparasitic resistance to benzimidazoles, tetrahydropyrimidines and macrocyclic lactones in developing countries	Gill, Kerr, Shoop, and Lacey (1998); Cezar et al. (2010); Kaplan and Vidyashankarb (2012)
Regulatory issues	The complex regulatory framework regulating Veterinary Medicinal Products is presently being revised	The EMA has recently launched an initiative to develop a framework for stronger collaboration between pharmaceutical industry and academia	Several issues related to pharmaceutical research and development in human and veterinary medicine can only be solved by interdisciplinary and transparent cooperation	EMA (2016); European Commission (2014)
Postgraduate training	Modern teaching techniques are invaluable tools for the continuous education of veterinary professionals	Topics of significance may differ from those developed in a more standard academic curriculum and could include strategies for finding and developing promising pharmacological candidates for use in animals	Continuous professional development should cover technical, scientific, regulatory and ethical developments and motivate professionals to participate in lifelong learning relevant to their profession	Directive 2013/55/EU

proteomics, drug residues monitoring and related screening techniques (Mochel et al., 2013);

- Contributing to the control of regulated therapeutics, including growth promoters and substances derived from genetic editing. This is also true for international standards, guidelines and rules that apply to sport animals. Achieving this goal requires international cooperation with and between the official bodies involved in regulating and controlling the marketing and use of VMPs, as well as the involvement of international antidoping organizations;
- Encouraging and supporting education, training and continuing professional education for future health care professionals working in veterinary and pharmaceutical practice, academia or industrial research and development.

It is a further goal of this new Network to encourage the European Commission to initiate calls for research in the area of veterinary medicines, under, for instance, Horizon 2020, and forming strong consortia for application to funding opportunities (IMI, EU-funding).

CONFLICT OF INTEREST

None of the authors of this manuscript has a financial or personal relationship with other people or organizations that could inappropriately influence or bias the content of the manuscript.

AUTHOR CONTRIBUTION

J. P. M. together with I. S. initiated the overall concept of the manuscript; provided passages with focus on veterinary issues; revised the temporary drafts and the final version of the manuscript. E. T.: provided passages with focus on issues related to veterinary antiparasitic medicines; revised the temporary drafts and the final version of the manuscript. K. H.: revised the temporary drafts and the final version of the manuscript with focus on research and development of veterinary medicines. J. C. V.: provided passages with focus on issues related to veterinary medicines; revised the temporary drafts and the final version of the manuscript. S. Ş.: provided passages with focus on pharmaceutical issues; revised the temporary drafts and the final version of the manuscript. L. D.: made available EUFEPS-related passages and -related references; revised the temporary drafts and the final version of the manuscript. R.T. C.: provided passages with focus on issues related to veterinary medicines; revised the temporary drafts and the final version of the manuscript. H. L.: made available EUFEPS-related passages and -related references; revised the temporary drafts and the final version of the manuscript. I. S.: corresponding author; together with J.P. M. initiated the overall concept of the manuscript; revised the temporary drafts and the final version of the manuscript.

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