Medical Communications and Writing for Patients

Editorial

Dear all,

As I'm sure you are aware, the field of medical writing for veterinary medicines is growing rapidly. If, like me, you know very little about this "new" field of writing, this issue's article from Cemile Jakupoglu and Sandra Götsch-Schmidt is an early Christmas present! Cemile and Sandra present "A short field guide to veterinary medical writing". Their excellent article explains, in easily digestible pieces, everything you need to know about veterinary medical writing as a profession, the different fields of this type of writing, how to get training in veterinary medical writing, and the upcoming trends in the area (please also be sure to pay attention to the journal's regular section on Veterinary Medical Writing!)

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As 2019 draws to a close, I hope that it has been a good year for you all. Enjoy the upcoming Christmas break – may your socks stay snowball-proof and may Santa be kind. See you in 2020! Bestest,

Lisa

A short field guide to veterinary medical writing



Since autumn 2018 there has been growing interest in veterinary medical writing (VMW) within the European Medical Writers Association (EMWA). But how can VMW be defined? An online search performed on 17 May 2019 for the term "veterinary medical writing" retrieved the EMWA journal article on "Opportunities in veterinary writing" (Parry, 2014)¹ and the EMWA Webinar "Veterinary Medical Writing same but different" (Götsch-Schmidt, 2018).2 Other search results consisted mainly of consultancy businesses offering VMW services or medical writing education. In this article, we will use the term 'veterinary writing' to refer to writing for the veterinary profession and 'veterinary writers' to refer to writers who produce veterinary-related materials as proposed by Parry (2014).¹

VMW as a profession

Veterinary medical writers play a crucial role in the pharmaceutical industry, associated consulting companies, contract research organisations, academic research and education, and governmental agencies. Veterinary writers do not need a degree in veterinary medicine; however, it is an advantage to have relevant educational background (such as biology or pharmacology that provides knowledge of mammalian physiology) as well as academic experience. Depending on the type of document to be written, biologists, chemists, other natural scientists and scientific translators have all found their niche in the veterinary writing field. On the other hand, veterinarians with scientific writing capabilities often find themselves employed within human healthcare sectors such as the pharmaceutical or medical device industries.

Fields of VMW

VMW is very diverse, even more so than medical writing in general. The reason for this is the number of species involved, stretching from A for "avian" to Z for "zoological" practice.

Veterinary writing comprises regulatory and non-regulatory, scientific and medical communication writing in different languages.¹ Veterinary regulatory and scientific research documents are normally composed in English. Other languages may be required for regulatory documents following national laws, like requests for animal testing; veterinarians hereby fulfil their role as custodians of animal welfare. Other areas where local languages are required include marketing communications, and study plans for non-English speaking assessors.

Veterinary regulatory writing aims to produce documents for the marketing authorisation of veterinary products, such as pharmaceuticals, vaccines, feed additives, or medicated feed; but it might also concern the evaluation of chemicals, biocides, or plant protection products. The latter overlaps with the typical work and writing areas for toxicologists.

Veterinary regulatory writing has to follow different laws and regulations, such as those of the European Medicines Agency (EMA) or the European Food Safety Authority to place a veterinary pharmaceutical product or feed additive on the market, respectively. In the case of toxicological laboratory animal studies ranging from acute toxicity to complex long-term carcinogenicity studies, OECD Test Guidelines³ must be followed. Accordingly, studies in animals can be conducted under different study standards. Academic research studies or early phase drug development studies might be conducted following Good Scientific Practice As a result of the limited training possibilities for VMW, a new special interest group for veterinary medical writing, "vet SIG", was launched at the EMWA conference in May 2019 in Vienna.

principles. Pivotal clinical trials in a specified animal species, the so-called target animal species, are usually conducted under Good Clinical Practice following VICH GL9.⁴ Toxicological studies or studies assessing drug residues in edible tissues might need to be conducted under Good Laboratory Practice.

VMW - same but different

The structure, content and terminology of medical writing used in the human healthcare sector can and should be broadly transferred to VMW. However, as presented in the EMWA webinar,² certain areas differ, like veterinary terminology (e.g., target animal species), routes of administration (e.g., intramammary), the assessment of residues in food producing animal species, and species specificity. Well-known examples of species specificity are permethrin toxicity in cats, occurring when products designated for dogs are improperly used in cats, and the fact that ruminants are generally not to be fasted. From a regulatory perspective, animal species can be categorised as "major" or "minor". In the EU, major species include cattle, sheep, pigs, chickens, salmon, cats, and dogs. The EMA has implemented a policy to address the lack of veterinary medicines for treating minor animal species and uncommon diseases in major animal species - a similar system as the orphan designation.5

Another consideration in VMW is that it includes aspects of human and environmental safety. Integrating human, animal and environmental health, the concept of "One World – One Health"⁶ guides the writing of submission dossiers for veterinary products. Residues in the environment and in edible tissues of food producing animal species, as well as antimicrobial resistance are evaluated for their potential impact on human safety. To address the human and environmental safety aspects, experts in ecotoxicology, analytical chemistry, and microbiology are needed.

Trends in VMW

As with human pharmaceuticals and medical devices, new rules, guidelines and regulations keep popping up in the veterinary field. In order to address different levels of public and animal health protection in the EU countries, the European Commission launched a revision of Directive 2001/82/EC in 2014 for a regulation on veterinary medicinal products. The main goals are to fight antimicrobial resistance, promote availability of veterinary medicinal products, and establish a modern, innovative, and fit-for-purpose legal framework. After 4 years of negotiations, on January 7, 2019, Regulation (EU) 2019/6 on Veterinary Medicinal Products was published.⁷ At the same time a new Regulation (EU) 2019/48 on medicated feed came in force in January 2019, which repeals Directive 90/167/EEC. The new Veterinary Medicines Regulation, or simply VMR, will apply from January 28, 2022. Much work has already begun with writing the 28 delegated and implementing acts, and on reports from the Commission. The clock to January 2022 is ticking.

The newly adopted VMR requires the authorities to establish and maintain a Union Database of veterinary medicinal products, also referred to as the "product database". At first the SPOR (Substance, Product, Organisation and Referential) task force⁹ was created for human areas only. However, various SPOR business cases were valid for both human and veterinary medicinal products, and it was decided that the task force membership would be spread amongst veterinary-specialised stakeholders.¹⁰ For medical writers, this means additional opportunities in the future to work as data managers.

Training in VMW

There is very little information or official training available for VMW, especially when compared to medical writing for human subjects. Basic training in European veterinary regulatory affairs is offered at the Organisation for Professionals in Regulatory Affairs (TOPRA)¹¹ or by other commercial training organisations. We have been on the lookout for training opportunities in *regulatory* medical writing, but for the most part have had to teach ourselves or receive in-house training.

The situation is somewhat better regarding veterinary medical communication training. There is limited guidance available specifically for *publication* writing in veterinary medicine (e.g., Christopher and Young, 2011).¹² Although most of the information provided in this aforementioned booklet is of a very broad and basic nature, it offers some practical tips specifically for VMW. For example, use the term "clinical signs", not "symptoms". (Symptoms are sensations felt and reported by human patients.) A variety of courses in research writing and veterinary scientific writing are available, as detailed in the publication by Christopher and Young (2015).¹³

The International Association of Veterinary Editors (IAVE) lists reporting guidelines and resources of particular relevance to animal research and studies (e.g., REFLECT, CONSORT, ARRIVE, STARTD, and SAMPL).¹⁴ In 2014, the IAVE conducted a survey on the awareness, knowledge, policies and views of veterinary journal Editors-in-Chief on reporting guidelines for research publication. The reported outcome sounds somewhat sobering when the authors state that "... many [editors] appear to have little or no knowledge of reporting guidelines".¹⁵

As a result of the limited training possibilities for VMW, a new special interest group for veterinary medical writing, "vet SIG", was launched at the EMWA conference in May 2019 in Vienna. As part of the goals defined at the first vet SIG meeting in Vienna, we would like to raise awareness of veterinary medical writing. So, keep an eye out for the publication of more information on the EMWA homepage (and in the Veterinary Medical Writing section in this journal), and please get in touch to learn about how you can get involved.

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