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Note on the regulation of veterinary medical devices in the EU: A review of the current situation and its impact on animal health and safety

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Abstract

Medical devices form a large heterogeneous group of products ranging from simple tools to medical testing and implants, the safety and efficacy of which are strictly regulated in all developed countries. Thanks to the health and cost benefits, medical devices have also found their way into veterinary medicine but, surprisingly, the regulation of these products is far less complex or, in some cases, missing altogether. Given the complexity and potential hazards of certain veterinary devices, the current state of affairs may lead to health and safety risks, both for animals and personnel involved. This review is the first to systematically map the current situation in the EU, revealing health and safety risks in practice for both animals and personnel involved and discussing them in a broader context. Only six out of the EU's 28 member states (Belgium, Croatia, Czech Republic, Germany, Hungary, and Slovakia) were found to have at least a degree of regulation of veterinary devices. As a result, a single product may be regulated as a veterinary medicinal product, a veterinary medical device or not be regulated at all, depending on the particular EU member state in question. As things stand, veterinary medicine makes use of all kinds of medical devices, including human products, regardless of their regulatory status and (pre-market) control. However, the use of such devices may influence the health and well-being of animals. Several measures are therefore suggested to attain the required levels of safety and efficacy surveillance for veterinary medical devices without creating excessive administration.

Keywords: *animal welfare, efficacy, European Union, regulation, safety, veterinary medical devices*

Introduction

An animal's quality of life is closely linked to the available veterinary services and products. Demand for products associated with human medicine has led to a plethora of medical devices being developed. To ensure a positive risk-benefit balance, these medical devices are subject to regulation in almost half WHO member states (World Health Organisation 2017) and there are ongoing efforts to create stable and co-ordinated regulation between those countries with the biggest market share (Tamura & Hiromu 2014).

Medical devices have also found their way into veterinary medicine. Their proliferation is driven by factors similar to human medicine, such as the availability of advanced technologies, higher expectations regarding the quality of services and ageing companion animals (Szkotnicki 2014). Additionally, greater numbers of both pets and livestock increase the threat of zoonoses and foodborne diseases, both of which support the development of novel veterinary medical devices for disease prevention, diagnosis, and treatment (Hunault 2017).

Despite the wide array of products, the regulatory issues of veterinary medical devices lag behind their human counterparts. In certain regions even products that carry the greatest potential risk, such as stents, endoprostheses or pacemakers remain unregulated. While in other cases, particular veterinary medical devices may be considered veterinary medicinal products leading to the highly illogical scenario of veterinary products being more strictly regulated than the corresponding human products (Thome-Kromer 2015). This lack of legislative clarity negatively influences the entire sector. From the users' point of view, clear information about the safety, efficacy, and quality of the product in question for the given species is missing (American Association of Equine Practitioners 2010) which makes the use of some products questionable and raises concerns with safety. From the manufacturers' point of view, the rules for product registration change from state-to-state and are often only available in the local language. Moreover, the identity of the responsible authorities may be unclear or hard to find, limiting the development and thus the availability of new products.

Veterinary physicians are able to use any of the human medical devices available on the global market. However, not all human devices are suitable for animals and some simply do not exist in a human version. Taken together, the list of medical devices exclusive to veterinary healthcare includes a wide range of products that display varying degrees of risk and are marketed as the sole responsibility of the manufacturer in a number of countries worldwide. If a veterinary practitioner decides to avoid this risk and use an approved human device, the drawbacks of this off-label use need to be considered, such as the lack of data on safety and efficacy in target species or the impossibility of reporting possible side-effects.

This review details the ongoing regulation of veterinary medical devices in the EU, discusses its impact on veterinary healthcare and suggests possible improvements to the current state of affairs. We chose the EU for several reasons. Firstly, it is the world's second largest producer of human medical devices after the US (Cunningham *et al* 2015). Secondly, the situation is especially complex because it involves application of national legislations in all 28 EU member states. Thirdly, the EU is currently strengthening its legislation on human medical devices (Migliore 2017) but veterinary devices remain unregulated (European Medicines Agency 2010; Government of Japan 2012; Roser & Warner 2014). Our data are based on a detailed survey among all the EU national competent authorities. Due to the vast differences between the regulation of 'common' and *in vitro* diagnostic medical devices (IVDs) that were quickly identified, this review is limited to the 'common' medical devices and ignores IVDs according to Regulation (EU) 2017/746. The 'common' devices normally represent up to 60% of the market and cover a wide range of products from simple bandages to X-ray machines or high-risk implantable products.

Medical devices in veterinary practice

The shift from one-person independent practices to large veterinary clinics and hospitals (Gauvin 2015) has seen veterinary practitioners begin using a range of products similar to their medical colleagues, including expensive equipment that was formerly rare (eg magnetic resonance imaging).

Products used in veterinary practice are either common human medical devices (off-label use) or veterinary devices designed specifically to treat animals.

Human medical devices

Veterinary medicine is notorious for its use of various human medicinal products, tools, and equipment. Since the activity of medical devices is based on general mechanical and physical principles, which are the same in humans and animals, the off-label use of human devices should not pose any hidden risk to animals. Based on the appearance and technical parameters of the product, veterinarians can decide relatively easily as regards its suitability for a specific procedure in any given species. Moreover, the quality, safety, and efficacy of human devices are tightly regulated in the EU (French-Mowat & Burnett 2012).

The off-label use of human medical devices in veterinary medicine is inspired by similar off-label use of medicinal products. The off-label use of human medicinal products is supported by law (otherwise also called a 'cascade' in the EU or 'extra-label use' in the US) and is a very practical and logical approach to dispensing medicine. Such justification, however, is missing for medical devices in the EU. The off-label use of human medical devices is thus regulated only on the national levels and each member state applies its own rules or delegates the entire responsibility to veterinarians.

Veterinary medical devices

Veterinary medicine treats many different patients of various characteristics and needs. Even though some veterinary devices are in fact simply the same versions of human products, but with a different label, a specialised veterinary version is sometimes needed because of differences related to:

- Body size (eg insulin pens with more precise dosing for pets, more powerful jet injectors for livestock, smaller retrieval baskets for extraction of kidney stones);
- Anatomy (eg differently shaped joint prostheses, stents, and orthoses, wheelchairs for dogs); and
- Physiology (eg specialised software for anaesthesia monitoring systems).

The human version of a device may not exist and veterinarians depend on the supply of unique veterinary products. Such devices are mostly used for:

- Animal identification (eg ear-tags, tattoo pliers, microchip implants);
- Intensive farming (eg tail dockers, dehorning pastes, electric and mechanical dehorners to prevent injuries, insemination guns, detectable needles to prevent meat contamination); and
- Other reasons (eg Elizabethan collars, wearables for continual monitoring of body functions).

Obviously, some devices, such as those for animal identification, have no direct health benefit for the animals and are used exclusively for reasons of practicality during breeding. Nevertheless, their design and risks' profile mirror those of the medical devices. In this instance, parallels can be drawn with aesthetic human products, such as breast implants. It was the infamous scandal with implants manufactured by Poly Implant Prosthese (France) that revealed the potential risk of these devices and contributed significantly to the development of the new Regulation (EU) 2017/745 on medical devices to better ensure their safety (Heneghan & Thompson 2012). Similar safety concerns may also be connected to the use of high-risk, non-medical veterinary devices.

Veterinary medical devices market

Veterinary medical devices are a relatively little known group of products. The aim of this section is to provide general information on their production compared to veterinary medicinal products and human medical devices and deliver much-needed context for the safety and efficacy issues discussed later.

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The global market

The global veterinary equipment market is valued at $US1.7 billion (Meticulous Research 2016). This represents less than 1% of the human market with human medical devices and the same ratio exists between the global markets with human and veterinary medicinal products. As for the geographic distribution of veterinary medical devices, reliable information is missing. It may be assumed that the situation resembles that of human medical devices, with them mostly being produced as well as consumed in the US. The second largest producer is the EU and the third Japan (LEK Consulting 2013). These three well-known leaders in innovation account for about 85% of the worlds' market (George 2010).

Key players

Increasing research and development costs lead to centralisation of pharmaceutical production leaving only a limited number of multinational companies active worldwide. Since the development of medical devices is faster and generally less demanding, the medical technology industry is still characterised by its high percentage of small enterprises. Statistics on the EU and the US producers of human medical devices show that more than 80% of the companies are small- and medium-sized enterprises with little sales revenue (Li *et al* 2015). On the other hand, centralisation slowly reaches this industrial segment as well. The top 1% of the companies account for more than 80% of global turnover indicating that large, diversified companies, such as Indexx Laboratories Inc, Neogen Corporation or Abaxis Corporation (all US) are active in the field and create most of the output. These companies are accompanied by the above-mentioned small enterprises which play a significant role in the ecosystem — they are engaged in the development of highly innovative medical technologies for narrow therapeutic niches. In veterinary medicine, the development and production of medical devices for less common animal species and breeds is crucial to ensure a good standard of veterinary care.

Future trends

The veterinary medical devices' global market is expected to grow at about 8% annually which is approximately double that of veterinary medicinal products. One of the key factors is the availability of modern technologies and methods adopted from human medical technology. The growth of the pet healthcare sector is further supported by the rising adoption of companion animals worldwide, increasing disposable income in urban populations and growing expenditures on pet healthcare. Companion animals are also ageing (approximately one-third of Canadian dogs and cats may be regarded as geriatric patients) and therefore suffering from chronic diseases which require new services and technologies to maintain a good quality of life (Szkotnicki 2014). The livestock healthcare technology is driven by the increasing number of food animals caused by growing meat consumption all over the world (Thornton 2010) and growing focus on continual monitoring, early diagnosis and disease prevention.

The information above indicates that currently veterinary medicine is open to new technologies and provides extensive opportunities for innovative companies and their products. However, the development of new products should be subject to appropriate regulatory surveillance to ensure that the veterinary medical devices do not simply become an easy exit strategy for companies that are unable to reach the market with human medical devices.

Current regulation of veterinary medical devices

As mentioned above, in contrast to human medical devices that are regulated in most countries worldwide (World Health Organisation 2017), only a small number of states regulate the quality and safety of veterinary medical devices. The crucial point is whether the basic definition of medical devices also covers veterinary use. For example, the US Federal Food, Drug, and Cosmetic Act defines a medical device as "an instrument… intended to affect the structure or any function of the body of man or other animals." The definition of veterinary devices sometimes extends beyond the scope of the human definition to cover devices for animal identification (eg in the Czech Republic and Slovakia).

Regulation worldwide

The world's regulation of human medical devices is being co-ordinated by sets of internationally accepted standards such as ISO 13485 on medical devices and by a voluntary organisation called International Medical Device Regulators Forum (Tamura & Hiromu 2014). Since regulation of veterinary devices is absent in many countries, the same efforts cannot be expected worldwide. In fact, only four of the world's top ten markets with human medical devices have a law which also covers veterinary medical devices. These are all the world's largest markets excluding the EU — US, Japan (Yahiro & Nakai 2004) and China (Ministry of Agriculture 2015). Interestingly, the existence of legislation on veterinary medical devices is not related to the overall economic strength of the country in question. For example, countries such as India (Central Drugs Standard Control Organization 2013), Mongolia (Mongolian State 2010) and Thailand (Yuwadee 2013) regulate these products while much more developed countries, such as Canada, Australia or France, do not. Nevertheless, the mere existence of a piece of legislation on veterinary medical devices does not guarantee its full enforcement.

A detailed survey on the worldwide regulation of veterinary medical devices is beyond the scope of this review. Briefly, each individual state differs greatly in its approach. Some regulate veterinary medical devices as medicinal products, others as medical devices (sometimes a simplified approach to human devices is applied) while the majority have no specialised rules. The regulation also depends on the product type. Generally, more rules apply to high-risk devices that are sterile, implantable or contain active substances.

Table 1 EU countries regulating veterinary medical devices.

Country	Responsible authority	Premarket requirements	Approved devices	
			List	Number
Belgium	Federal Agency for Medicines and Health Products	Yes	No	–
Croatia	Agency for Medicinal Products and Medical Devices	Yes	No	–
Czech Republic	Institute for State Control of Veterinary Biologicals and Medicines	Yes	Yes	~ 210
Germany	Federal Office of Consumer Protection and Food Safety	No	No	–
Hungary	Directorate of Veterinary Medicinal Products	Yes	Yes	~ 40
Slovakia	Institute for State Control of Veterinary Biologicals and Medicaments	Yes	Yes	~ 1,000*

* Including veterinary preparations.

Regulation in the EU — union level

The requirements for human medical devices in the EU have been described multiple times elsewhere. Medical devices entering a single EU market require a CE mark indicating their compliance with the current law (van Drongelen *et al* 2015). For high-risk devices, manufacturers must gain approval from a designated third party (so-called notified body) to use the CE mark. Recently, Regulation (EU) 2017/745 was introduced to tighten the approval of medical devices, thereby ensuring better safety.

Despite strengthening the regulation of human medical devices, there is no regulation of their veterinary counterparts at an EU level. The only set of rules, Directive 84/539/EEC, was replaced by Directive 2008/13/EC in 2008 since internal market function and protection of users and animals could be better served by this new community legislation. It was based on the notion that the majority of devices were manufactured for both human and veterinary use and after meeting relatively strict requirements on human devices, they were suitable to treat veterinary patients. The devices designed solely for animal use, therefore, remained unregulated. This had a variety of negative consequences such as complicating the process of exporting veterinary medical devices into countries that regulate these products (Government of Japan 2012). The European Medicines Agency (2010) also stipulated the need for comprehensive veterinary regulation but, thus far, no progress has been achieved.

Despite the information above, veterinary medical devices do not operate within a full regulatory vacuum. They are subject to general Directive 85/374/EEC on product liability or Directive 2001/95/EC on general product safety. The devices which fall under the Directive 2014/30/EU on electromagnetic compatibility must comply with this directive and must have the CE mark to demonstrate compliance. However, this directive has not been designed to evaluate all the properties of veterinary medical devices that are important for veterinary care, including their quality, safety, and efficacy in the given species.

Regulation in the EU — national level

The missing EU regulation for veterinary medical devices allows each member state to apply their own rules for such products. The increasing number of questions about veterinary medical devices led Dr Bertani from the Italian Directorate-General for Animal Health and Veterinary Medicinal Products to conduct a survey among the other EU authorities. The results showed that 80% of the authorities had received inquiries about veterinary medical devices but approximately 70% of them were unaware of any national regulation and felt a degree of central regulation would be useful (Bertani 2017).

Since this Italian research did not reveal any details, we conducted another survey. Competent authorities regulating veterinary medicinal products (in some cases also human medical devices or biocides) were asked about national regulation of veterinary medical devices. A total of 36 authorities were questioned and 30 answers from 26 EU member states were received. We found that only six EU member states regulate veterinary medical devices. The details of the regulation in these states can be seen in Table 1. According to the authors' best knowledge, the information presented below illustrates precisely the current regulatory environment in the EU. However, two limitations should be considered: i) two EU member states, Spain and Malta, did not respond to our survey; and ii) some of the authorities were not certain about the (non) existence of the rules on veterinary medical devices in their countries.

Belgium

Selected high-risk veterinary medical devices, such as sterile, implantable or antiseptic devices are regarded as medicinal products and therefore regulated. However, the regulation is not so strict as compared with the standard medicinal products and veterinary medical devices are not even listed in the new database of medicinal products. The authority only requires the data on the quality, biocompatibility, and sterility (if applicable). More information can be found in the Royal Decree of 6 June 1960 on the Manufacture, Preparation and the Wholesale Distribution and Delivery of Medicinal Products which is available in French and Dutch. Veterinarians are allowed to use CE-marked human medical devices to treat animals in Belgium.

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Croatia

The Croatian definition of veterinary medical devices covers products similar to the standard EU definition of human medical devices. Prior to marketing, manufacturers or their representatives with a registered office in Croatia, must demonstrate device compliance with applicable statutory requirements, Croatian and EU standards and register their business in the list of manufacturers available online. Detailed information can be found in the Act on Veterinary Medicinal Products which is also available in English.

Czech Republic

The Czech definition of veterinary medical devices covers all products like the standard EU definition of human medical devices and implantable products for animal identification. Before marketing, manufacturers need only declare basic information such as the device details, package insert or the conformity with related laws. Afterwards, adverse effects must be reported. The relevant Act No 290/2003 Coll on Non-Medicinal Veterinary Products and Veterinary Medical Devices is available only in Czech but the basic requirements in English can be found on the authority website.

Germany

The regulation of veterinary medical devices in Germany is similar to that in Belgium. Selected high-risk devices, namely implantable devices, surgical sutures, single-use instruments for microbial burden reduction and wound dressings are regarded as 'fictional drugs' and therefore regulated. These 'fictional drugs' (Fiktive Arzneimittel) are privileged as compared to standard medicinal products (there is no pre-market approval, labelling requirements, etc). More information can be found in the Medicinal Products Act from 12th December 2005 which is also available in English.

Hungary

Devices for veterinary manipulation, diagnostic examination, and animal identification that are in direct contact with the animals' body are regulated according to the Regulation 128/2009 (X6) MARD on Veterinary Medicinal Products. The regulation is available only in Hungarian, but guidance can also be obtained in English. The most important requirements include the data on quality and stability, proposed product leaflet and labels in Hungarian. The approved devices can be found on the authority website in a small database which currently contains products mostly for animal identification.

Slovakia

The Slovak definition of veterinary medical devices covers the same products as the Czech definition. The authority requires general information about the product, its clinical evaluation, safety, etc. If applicable, the compliance with corresponding international standards, such as the ISO 11784, needs to be proved. Afterwards, the product is added into a publicly available database of veterinary medical devices and preparations. More information can be found in the recent Act No 17/2018 Coll, on Veterinary Preparations and Veterinary Medical Devices which is available only in Slovak, but the most important forms can also be found in English. Veterinarians are allowed to treat animals with human medical devices.

Examples of regulation of veterinary medical devices

None of the EU member states officially divide veterinary medical devices into the risk classes but, in reality, the low- and high-risk devices are treated differently. The low-risk devices are regulated only in countries having regulatory rules designated to veterinary medical devices (eg basic bandages that are regulated in the Czech Republic). The low-risk products that would be marketed in most of the EU countries are difficult to find, indicating that low barriers to enter the market support smaller companies operating regionally. Moreover, the demand for these low-risk veterinary devices is relatively lower because they can be easily substituted by CE-marked human medical devices that are already available throughout the EU.

As for the high-risk medical devices, the situation is different because they often have special features that cannot easily be secured by human products. The existence of such products is thus important to maintain a good quality of veterinary healthcare. Since many of these devices are naturally perceived as high-risk products, the push for some kind of registration is stronger. This is particularly obvious in so-called borderline products containing active substances (European Commission 2017). As a categorisation of veterinary medical devices does not exist in the EU and these products are often sold in multiple member states, different levels of scrutiny exist. Three brief examples of the real products currently available in the EU are described below:

• Antiseptic dressings — an antiseptic dressing is registered as a veterinary medicinal product (eg UK), veterinary medical device (eg Czech Republic) or not regulated at all (eg Greece). Comparable human products are considered as class III medical devices (European Commission 2010) and are therefore subject to the most rigorous device regulation that requires full quality control, comprehensive clinical data, etc.

• Caustic products — a caustic pencil is manufactured in both human and veterinary versions with identical composition. The human version is regulated as a human medicinal product. The veterinary version is not regulated or regulated as a veterinary medical device (eg Czech Republic) depending on the EU member state.

• Insulin pens — an insulin pen for companion animals can be purchased in more than 15 EU countries. The product is regulated either as a veterinary medical device (eg the Czech Republic and Slovakia) or not regulated. Human insulin pens are regarded as class IIb medical devices (European Commission 2010).

Possible risks

Limited market control may result in decreased safety and efficacy (device failure). One of the most important sources of possible risks is the analysis of reported adverse events. Unfortunately, under-reporting of adverse events is a common problem even for otherwise tightly regulated veterinary medicinal products (De Briyne 2017). The following paragraphs summarise commonly mentioned risks of veterinary medical devices along with some anecdotal evidence found in the literature. The risks for animals are followed by risks for humans to illustrate the unsatisfactory nature of the current situation.

Risks for animals

Research articles provide evidence of both safety and efficacy issues experienced by animal patients. Such cases include material failure of a tracheal stent (Rosenheck *et al* 2017), infections after implantation of urinary stents (Dunn & Berent 2017), wound dehiscence caused by broken sutures, etc. In general, the nature of these events closely resembles those experienced by human patients after using human medical devices.

Risks for humans

Similar to veterinary medicinal products, veterinary devices also pose a potential threat to healthcare providers — veterinarians, breeders, and owners. Even though their primary mode of action is not pharmaceutical, immunological or metabolic, devices made from unsuitable materials may release substances and thus contaminate food products. This is even more significant for substance-based devices, such as ear and eye drops, lubricants or liquid bandages. Preservatives, solvents and other substances released from these products may leave traces or even accumulate in animal tissue and remain unnoticed because of the missing control of maximum residue limits. Last but not least, veterinary medical devices can harm people in other ways: inappropriate design, inadequate instructions, and users' carelessness may lead to lacerations and punctures (needles, surgical tools), chemical and thermal burns and cuts (different kinds of dehorners) or well-known injuries to the hands and digits caused by high-pressure jet injectors (Verhoeven & Hierner 2008).

Animal welfare implications and conclusion

Animal welfare is influenced by the quality and availability of veterinary tools and equipment. While the quality, safety, and efficacy of human medical devices are strictly regulated in most countries worldwide, including the EU, only six EU members also regulate veterinary medical devices. Such regulation is mostly simpler and sometimes only formal when compared to human devices. In the remaining EU countries, veterinary devices are not subject to any regulation. Interestingly, this does not always mean a simpler introduction to the market because veterinary medical devices may easily become veterinary medicinal products by presentation (medical claims) or, less frequently, by their function (pharmacological, metabolic or immunological) (European Medicines Agency 2010; Thome-Kromer 2015). The situation is further complicated by the missing list of EU authorities responsible for the surveillance of veterinary medical devices.

From the user's perspective, the safety and efficacy of veterinary medical devices are not controlled in most EU countries and post-marketing surveillance is not required even in the countries that regulate these products. The information on the veterinary medical devices' failures is thus scarce and difficult to find so the stakeholders are not able to react in a timely manner. Taken together, the current situation is complicated and raises concerns for animal welfare.

The recent Regulation (EU) 2017/745 on human medical devices greatly increases the resources (knowledge, time and money) necessary to introduce human devices into the market. The process starts to resemble the development of medicinal products. The pharmaceutical industry is characterised by steady consolidation and a rising market share held by large companies (Kesic 2011). We do not think that veterinary medical devices should be regulated in such a way as to potentially threaten the existence of small- and medium-sized producers.

The market analysis clearly shows the importance of small companies producing specialised devices for less frequent indications or less popular species. The excessive regulation would lead to perishing of such companies and thus negatively influence the availability of these products. It is also worth noting that the existence of small enterprises is more important in the veterinary rather than human market due to its fragmentation by species and breeds. On the other hand, it seems inappropriate to leave medical devices for animals without control. Therefore, the following measures are suggested: firstly, co-ordinated rules introducing basic safety and efficacy control of high-risk devices should be adopted. This should create equal conditions for all companies within the EU and resolve the current safety and efficacy issues of the products with the greatest risk potential. Secondly, the low-risk devices should be marketed on manufacturers' sole responsibility within the whole EU. This would decrease the administrative burden, support small and emerging enterprises and promote innovation without creating serious safety concerns. Finally, stakeholders should be given the opportunity to report adverse effects of all veterinary devices into a central database. This would be a neat and effective solution to achieving gradual discontinuation of the utilisation of products with negative risk/benefit ratios. We believe that such measures could be sufficient to improve the current situation without compromising the safety and availability of veterinary medical devices and thus favourably influence animal welfare in the long term.

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