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.