The Old School, Brewhouse Hill, Wheathampstead,
Hertfordshire AL4 8AN, UK
www.ufaw.org.uk

Animal Welfare 2020, 29: 37-43
ISSN 0962-7286
doi: 10.7120/09627286.29.1.037

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

H Potockova[*†‡], *P Kusnierik*[§] *and J Dohnal*[‡]

[†] Bioinova, s.r.o., Vídeňská 1083, 14200 Prague, Czech Republic
[‡] Department of Applied Pharmacy, Faculty of Pharmacy, University of Veterinary and Pharmaceutical Sciences Brno, Palackého 1, 612 42 Brno, Czech Republic
[§] Contipro a.s., Dolní Dobrouč 401, 56102, Dolní Dobrouč, Czech Republic
* Contact for correspondence: Hana.potockova@bioinova.cz

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*