Regulatory Policies, Education and Training in Veterinary Pharmaceutical Sciences

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To my Family,

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Abstract

The responsibility to provide high-quality pharmaceutical care for animal patients challenges pharmacist knowledge regarding indications, dosages and drug administration. The aim of the study is to develop a regulatory and an academic framework in veterinary pharmaceutical sciences.

The methodology is divided into two parts. In Part I three questionnaires were developed and disseminated to veterinary surgeons, pharmacists and pet owners to identify the perception of the role of the pharmacist in animal care and challenges of access to medicines. Data generated from the questionnaires was used to design a training programme validated using a modified e-Delphi method, for pharmacists. In Part II the regulatory framework for veterinary medicinal products was analysed by comparing Directive 2001/82/EC, Regulation (EU) 2019/6 and Directive 2001/83/EC. A separate questionnaire to identify the resources required by a National Competent Authority (NCA) to assess veterinary medicinal products, to provide medicines information and to collaborate with other entities was disseminated to EU NCAs that regulate veterinary medicinal products.

Respondents from Part I consisted of 21 veterinary surgeons, 92 pharmacists, and 232 pet owners. Seventeen veterinary surgeons prescribed human medicines for use in animals because the veterinary medicinal product needed was not available. Pharmacists were perceived as unprepared to safely dispense and provide advice for medication use in animals by 61 pharmacists, 16 veterinary surgeons and 122 pet owners. Pharmacists (n=68) and veterinary surgeons (n=16) agreed that pharmacists should be trained in veterinary pharmaceutical sciences. Pet owners (n=171) would be more willing to ask a

pharmacist for advice if they can be sure that the pharmacist is knowledgeable. The developed validated training programme consists of three main areas, namely veterinary disease states, veterinary pharmacotherapy, and regulation of veterinary medicinal products. In Part II, the analysis of the legal framework showed that the requirements for the dossier for human and veterinary medicinal products are similar. Respondents included ten NCAs. Seven NCAs had a dedicated department, with varying areas of expertise, for veterinary medicines. One NCA indicated that the staff worked in an integrated manner with both veterinary and human medicines. Training for assessors was provided by six NCAs. A proposal for the setup of a support office within a regulatory entity specialised in human medicines to include the assessment of veterinary medicinal products and medicines information in its remit was developed.

The trust in the pharmacist taking an active role in animal care could be improved in the fifty-two percent of veterinary surgeons and fifty-three percent of pet-owners who had reservations. Trained pharmacists should strengthen their role with veterinary surgeons and pet owners. Interdisciplinary collaboration provides the best care for animal patients and improves access to safe and effective medicine. The analysis of the regulatory framework and the reflection of the questionnaire for NCAs provides a basis to support the establishment for a support office within an entity specialised in human medicines to include veterinary medicines. Pharmacists should be the drivers to enact change as illustrated in the veterinary-pharmacy bicycle paradigm where trained pharmacists combined with a robust regulatory framework will help in achieving excellence in veterinary services.

Keywords: education, interdisciplinary collaboration, perception, training, veterinary medicines, veterinary pharmacy

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Glossary

Common Technical Document	A document consisting of five modules which contains the quality, safety and efficacy information of a medicinal product for human use. Reference: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). M4: The Common Technical Document [Internet]. [cited 202020 May 28]. Available from: https://www.ich.org/page/ctd.
Content validity	The degree to which an instrument has an appropriate sample of items for the construct being measured. Reference: Polit DF, Beck CT. Nursing research: Principles and methods. 7th edition. Philadelphia: Lippincott, Williams, & Wilkins; 2004. p. 423.
Directive	A Directive lays down objectives that must be achieved by EU countries but leave the country free on how to achieve the objectives. Directives must be transposed into the national law. Reference: European Commission. Types of EU law [Internet]. Belgium: European Commission; [cited 2020 May 28]. Available from: https://ec.europa.eu/info/law/law-making-process/types-eu-law_en.
Marketing authorisation	An authorisation required for a medicinal product to be placed on the market of a Member State which has been issued by the competent authorities of that Member State in accordance with Directive 2001/83/EC. Reference: European Commission. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [Internet]. Official Journal of the European Communities 2001; L311:1-62 [cited 2020 May 28]. Available from: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PD.
Metaphylaxis	The administration of antimicrobial agents to clinically healthy animals that belong to the same herd, flock or are in the same pen as animals showing clinical signs of infection to prevent them from developing clinical signs and prevents the further spread of disease. Reference: European Medicines Agency (EMA). Question and answer on the CVMP guideline on the SPC for antimicrobial products (EMEA/CVMP/SAGAM/383441/2005) [Internet]. EMA; 2016 [cited 2020 Jun 19]. Available from: https://www.ema.europa.eu/en/documents/other/question-answer-cvmp-guideline-summary-product-characteristics-antimicrobial-products_en.pdf.
Prophylaxis	The administration of antimicrobial agents to prevent the development of infection. Reference: Enzler MJ, Berbari E, Osmon DR. Antimicrobial prophylaxis in adults. Mayo Clinical Proceedings 2011;86(7):686-701.

Regulation	A legal act that applies automatically within each Member State. Regulations do not need to be transposed into national law but must be applied as is. Reference: European Commission. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [Internet]. Official Journal of the European Communities 2001; L311:1-62 [cited 2020 May 28]. Available from: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PD.
Veterinary Medicinal Product	Any substance or combination of substances which may be administered to animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product. Citation: Ministry for Justice, Culture and Local Government. Subsidiary Legislation 437.47 Veterinary Medicinal Products Regulations [Internet] Malta: The Ministry 2004: 1-103 [cited 2020 May 28]. Available from: http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10983&l=1.

List of Abbreviations

CTD	Common Technical Document
CVI	Content Validity Index
DCP	Decentralised Procedure
EEA	European Economic Area
EMA	European Medicines Agency
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
FDA	U.S. Food and Drug Administration
FIMEA	Finnish Medicines Agency
FREC	Faculty of Medicine and Surgery Research Ethics Committee
GMP	Good Manufacturing Practice
MRP	Mutual Recognition Procedure
NCA	National Competent Authority
NVL	National Veterinary Laboratory
USA	United States of America
VMS	Veterinary Medicines Section
VPRD	Veterinary and Phytosanitary Regulation Department

Chapter 1

Introduction

1.1. Background

This research is concerned with the regulation of veterinary medicinal products at a European and National level. The collaboration between veterinary surgeons and pharmacists, pharmacist involvement in veterinary pharmacy practice, the challenges encountered and the impact of education and training in veterinary pharmaceutical sciences are discussed.

1.2. Evolution of Veterinary Medicine: a Timeline

Veterinary medicine is "the science that deals with the maintenance of health in animals, and the prevention, alleviation and cure of disease and injury."[1] The practice of providing medicinal therapy to animals dates back to 3000BC and has evolved into a speciality area of pharmacy practice with a wide variety of practice settings (Davidson, 2019). Veterinary pharmacists can be found practicing in veterinary teaching hospitals, veterinary practices, community pharmacies, the pharmaceutical industry, academia and governmental entities (Lust 2003; Davidson, 2019). Table 1.1 gives an overview of the timeline of events linked to the evolution of veterinary medicine.

[1] Merriam-Webster. Veterinary Medicine [Internet]. USA: Merriam-Webster, Incorporated; [cited 2020 May 03]. Available from: merriam-webster.com/medical/veterinary%20medicine

Table 1.1: Timeline of the evolution of veterinary medicine

BC	c. 3000	Mesopotamia: a man named Urlugaledinna was known as an expert in healing animals[2]
	2200	Babylonia: Code of Hammurabi: a legal code that laid down the concept of veterinary fees[2]
	400:	Greece: Hippocrates' work on humoral pathology affected veterinary practice and human medicine for 2000 years[3]
AD	900	England: Anglo-saxon Leech Book describes animal cures[3]
	1490	Spain: First short-lived veterinary schools established[3]
	1720	England: Surgeon-farrier advances humane treatments, rational medication-use and education[3]
	1761	France: Start of the veterinary profession after founding first college of veterinary medicine in Lyon[3]
	1791	England: Start of British veterinary profession[3]
	1852	USA: Establishment of first veterinary college in Philadelphia[3]
	1953	USA: FDA creates a veterinary medical branch within the Bureau of Medicine[3]
	1965	USA: Bureau of Veterinary Medicine established[4]
	1984	USA: Bureau of Veterinary Medicine changes to Center for Veterinary Medicine [4]
	1994	USA: Animal medicinal drug use clarification act allows veterinary surgeons to prescribe human drugs off-label for use in animals[4]
	1995	Europe: Establishment of the European Medicines Agency to ensure safety and efficacy of veterinary and human medicines across Europe[4]

[2] Royal College of Veterinary Surgeons (RCVS) Knowledge. Global veterinary medicine timeline [Internet]. UK: RCVS; 2017 [cited 2020 May 20]. Available from: https://knowledge.rcvs.org.uk/heritage-and-history/history-of-the-veterinary-profession/global-veterinary-medicine-timeline/.

[3] U.S Food and Drug Administration (FDA). Center for Veterinary Medicine History [Internet]. USA: FDA; 2018 [cited 2020 May 20]. Available from: https://www.fda.gov/about-fda/history-fdas-centers-and-offices/center-veterinary-medicine-history.

[4] European Medicines Agency (EMA). History of EMA [Internet]. UK: EMA; 2015 [cited 2020 May 20]. Available from: https://www.ema.europa.eu/en/about-us/history-ema.

1.3. Regulation of Veterinary Medicinal Products

Veterinary medicinal products are substances, or combinations of substances, used in animals for the treatment, prevention or diagnosis of disease by restoring, correcting or modifying physiological functions through pharmacological, immunological or metabolic actions.[5]

Medicated feed is a means of administering medicinal products to farmed animals, aquaculture species and pets under controlled conditions, against a veterinary prescription. It is a mixture of food and medicinal product and in some cases, it is the most effective way to administer medication to animals.[5]

The European Union (EU) supports the development and authorisation of veterinary medicinal products that are safe, effective and of high-quality ensuring the availability of medicinal products and safeguarding public health, animal health and the environment. The legislation in place sets standards to achieve these goals.[5] Appendix 2 outlines the evolution of European law for veterinary medicinal products and medicated feed.

Authorisation procedures for veterinary medicinal products across the EU have been in place since the mid-90s. The system is supported by the European Medicines Agency (EMA).[5] Veterinary medicinal products can be authorised or registered through either one of five routes:

[5] DG Health and Food Safety: Animal nutrition, veterinary medicines. Veterinary Medicines and Medicated Feed [Internet]. Belgium: European Commission; [cited 2020 Jun 05]. Available from: https://ec.europa.eu/food/animals/health/veterinary-medicines-and-medicated-feed_en.

1. Medicinal products are authorised in all EU member states and the European Economic Area (EEA) simultaneously through a centralised marketing authorisation.[6]
2. Medicinal products may be authorised in several member states via a Mutual Recognition Procedure (MRP) or a Decentralised Procedure (DCP). For a MRP to be applicable, the medicinal product must be authorised in at least one EU/EEA country. Other member states recognise the authorisation of the other country. The DCP applies when there is no existing marketing authorisation in the EU and the medicinal product is to be authorised in one or more member states simultaneously.[6]
3. Medicinal products which have a National Marketing Authorisation are only authorised in one single member state.[6]
4. Veterinary medicinal products that have a valid marketing authorisation in a source EU/EEA country may be marketed, or administered, in another member state if a health situation so requires.[7]
5. An exemption scheme is introduced for the national authorisation of veterinary medicinal products that are intended to be used only in small non-food animals and pets including aquarium animals, terrarium animals, cage birds, homing/racing pigeons, small rodents and ferrets. This excludes dogs and cats.[8]

[6] European Medicines Agency (EMA). The European Regulatory System for Medicines [Internet]. The Netherlands: European Medicines Agency; 2014 [updated 2017 Feb 1; cited 2020 Jun 19]. Available from: https://www.ema.europa.eu/en/documents/leaflet/european-regulatory-system-medicines-european-medicines-agency-consistent-approach-medicines_en.pdf

[7] Ministry for the Environment, Sustainable Development and Climate Change. Information about the authorisation or registration routes (Version 2) [Internet]. Malta: Veterinary and Phytosanitary Regulation Department; 2019 [updated 2019 Feb 15; cited 2020 Jun 19]. Available from: https://agriculture.gov.mt/en/nvl/Documents/authLicSchemes/authorisationRoutes.pdf.

[8] Ministry for the Environment, Sustainable Development and Climate Change. Information about the authorisation or registration routes (Version 2) [Internet]. Malta: Veterinary and Phytosanitary Regulation Department; 2019 [updated 2019 Feb 15; cited 2020 Jun 19]. Available from: https://agriculture.gov.mt/en/nvl/Documents/authLicSchemes/authorisationRoutes.pdf.

1.4. Regulation of Veterinary Medicinal Products in Malta

In Malta, the Veterinary Services Act[9] was first enacted in 2001 to establish requirements on the veterinary field, for veterinary medicinal products, feedingstuffs, zootechnical requirements and for regulation of the veterinary profession. Directive 2001/82/EC was transposed into Subsidiary Legislation 437.47 Veterinary Medicinal Products Regulation[10], under in Maltese Law to comply with the European Community Code relating to veterinary medicinal products, in 2004. The regulations within this law apply to all veterinary medicinal products in Malta. This also includes pre-mixes for medicated feeding stuffs that are intended to be placed onto the Maltese market and are prepared by methods involving one or more industrial processes.[10]

Veterinary medicinal products fall under the remit of the Veterinary Medicines Section (VMS) while medicated feed falls under the remit of both the Veterinary Medicines Section as well as the Animal Nutrition section due the nature of its composition. The regulation of vitamins, shampoos, non-medicated creams, dog collars, biocides, diagnostic tools and medical devices does not fall within the remit of the VMS and they do not require a marketing authorisation to be placed on the market. These products are either not regulated or regulated by other entities. [11]

[9] Ministry for Justice, Culture and Local Government. Chapter 437 Veterinary Services Act [Internet] Malta: The Ministry 2002: 1-38 [cited 2020 May 21]. Available from URL: http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8903&l=1.
[10] Ministry for Justice, Culture and Local Government. Subsidiary Legislation 437.47 Veterinary Medicinal Products Regulations [Internet] Malta: The Ministry 2004: 1-103 [cited 2020 May 21]. Available from URL: http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10983&l=1.
[11] Ministry for the Environment, Sustainable Development and Climate Change. Frequently asked questions (FAQ) on veterinary medicinal products and the Veterinary Medicines Section (VMS) (Version 2) [Internet]. Malta: Veterinary and Phytosanitary Regulation Department; 2019 [updated 2019 Feb 15; cited 2020 May 21]. Available from: https://agriculture.gov.mt/en/nvl/Documents/usefulInfo/faq.pdf.

The VMS is the National Competent Authority (NCA) for veterinary medicinal products. It forms part of the National Veterinary Laboratory (NVL) within the Veterinary and Phytosanitary Regulation Department (VPRD) within the Ministry for Agriculture, Fisheries and Animal Rights. The VMS recommends to the Director General on the granting, withdrawing, suspension and/or revocation of authorisations or registrations of veterinary medicinal products. Inspections of veterinary wholesalers and veterinary pharmacies, medicated feed traders and feed mills and Good Manufacturing Practice (GMP) inspections are also carried out. It is within the remit of the VMS to determine the method of supply of veterinary medicinal products in Malta. The VMS contributes to the EMA network to optimise resources, share resources within the network and implement decisions required by the European Commission.[12]

1.5. Local Veterinary Pharmacy Services

There are thirteen registered veterinary pharmacies in Malta and nineteen registered veterinary wholesale dealers. Only veterinary wholesale dealers that are approved by the Veterinary Medicines Section (VMS) can import, procure and/or distribute veterinary medicinal products while only veterinary pharmacies are approved to sell veterinary medicinal products.[13]

Legally, pharmacists are able to dispense veterinary prescriptions and sell veterinary medicinal products by virtue of their registration as a pharmacist with the Pharmacy

[12] Ministry for Agriculture, Fisheries and Animal rights. Mission Statement [Internet]. Malta: National Veterinary Laboratory; 2020 [cited 2020 May 21]. Available from: https://agriculture.gov.mt/en/nvl/Pages/missionStatement.aspx.

[13] Ministry for Agriculture, Fisheries and Animal Rights. List of Main Stakeholders as of 21-02-2020 [Internet]. Malta: Veterinary and Phytosanitary Regulation Department; 2020 [cited 2020 May 03]. Available from: https://agrifish.gov.mt//en /nvl/documents/stakeinfo/mainstakeholders.pdf.

Council. There are no extra qualifications necessary for a pharmacist to provide a veterinary pharmacy service.

1.6. Changes in the Regulation of Veterinary Medicinal Products

The current legislation governing veterinary medicinal products and medicated feed has been replaced by Regulation (EU) 2019/6 and Regulation (EU) 2019/4 respectively. Regulation (EU) 2019/16 of the European Parliament and of the Council of 11 Dec 2018 on veterinary medicinal products and repealing Directive 2001/82/EC has been published in January 2019. The regulation will be implemented on the 28 January 2022.[5]

Limitations for the current legal framework have been identified over time. The limitations concern the availability of medicines for limited markets and a lack of innovation associated with a heavy administration burden for authorisation procedures.[14] The new regulation will update the existing laws on the authorisation, use, access and safety of veterinary medicinal products within the EU. Other objectives of the regulation include stimulating the development of innovative products for small markets, such as veterinary medicinal products with minor use or for minor species and improve functioning of the internal market.[15] An important objective of the new regulation (Regulation (EU) 2019/6) is to strengthen the action to fight antimicrobial resistance.

[5] DG Health and Food Safety: Animal nutrition, veterinary medicines. Veterinary Medicines and Medicated Feed [Internet]. Belgium: European Commission; [cited 2020 Jun 05]. Available from: https://ec.europa.eu/food/animals/health/veterinary-medicines-and-medicated-feed_en.

[14] Council of the European Union. Veterinary medicines: new EU rules to enhance availability and fight against antimicrobial resistance [Internet]. Belgium: Council of the European Union; 2018 [cited 2020 May 21]. Available from: https://www.consilium.europa.eu/en/press/press-releases/2018/06/13/veterinary-medicines-new-eu-rules-to-enhance-availability-and-fight-against-antimicrobial-resistance/.

[15] European Medicines Agency (EMA). Implementation of the new Veterinary Medicines Regulation [Internet]. The Netherlands: European Medicines Agency; 2020 [cited 2020 May 25]. Available from: https://www.ema.europa.eu/en/veterinary-regulatory/overview/implementation-new-veterinary-medicines-regulation.

Antimicrobial resistance is becoming a great concern and efforts to combat this threat have been stepped up through measures that ensure prudent and responsible use of antimicrobials in animals. Addressing the problem of antimicrobial resistance should take a 'One Health' approach (Kahn, 2017; McEwan and Collignon, 2018).

1.7. Integrating Pharmacy Practice: One Health

The concept of 'One Medicine' was started by a German physician in the 19th century who believed that there should not be a dividing line between human and veterinary medicine as they are interdependent (Osbourn et al., 2009; McDowell et al., 2017). This concept has evolved to include the health of the environment and the ecosystems within it and is termed 'One Health' (Osbourn et al., 2009; Zinsstag, 2011; Gyles, 2016; Destoumieux-Garzón et al., 2018).

One Health is an international initiative that strives to improve the health and wellbeing of humans, animals and their environment (McDowell et al., 2017). This is possible with the collaboration or veterinary surgeons, doctors and ecologists to find solutions for global health challenges. Pharmacists' contribution to One Health is largely due to their knowledge, training and accessibility within the community (McDowell et al., 2017).

In Malta, the concept of One Health is endorsed by the VMS, by actively participating in the international strategy against the rising threat of antimicrobial resistance. The VMS regard the prudent use of antibiotics and veterinary medicinal products, including their residues in food-producing animals, as an important issue.[16]

[16] Ministry for Agriculture, Fisheries and Animal rights. Mission Statement [Internet]. Malta: National Veterinary Laboratory; 2020 [cited 2020 Jun 06]. Available from: https://agriculture.gov.mt/en/nvl/Pages/missionStatement.aspx.

1.8. Collaboration Between Pharmacists and Veterinary Surgeons

The judicious use of medicines is of paramount importance. This is especially true with respect to antimicrobial agents due to the emerging resistance and multidrug resistant organisms. Pharmacists and medical practitioners have developed beneficial interprofessional collaboration in the field of human medicine. A similar collaboration may be considered between veterinary surgeons and pharmacists (O'Driscoll et al., 2014b). Pharmacists are uniquely positioned to encourage safe and effective medicine use without discrimination among different species (O'Driscoll et al., 2014b; Theberge and Sehgal, 2016).

In some cases, using medicinal products in once species impacts the effective treatment on another. As an example, colistin is an antibacterial agent that is used to treat multidrug resistant infections in humans and its use in animals is widespread. The development and spread of resistance to this antibacterial agent may lead to treatment failure in humans (Zavascki, 2009; O'Driscoll et al., 2014b).

The growth of veterinary pharmacy is enabling pharmacists to apply their knowledge to veterinary scenarios. Pharmacists could provide advice to veterinary surgeons regarding new developments in human pharmaceutical products and discuss advantages and disadvantages of off-label use (Lust, 2009). Many pharmacists have access to drug information resources that can be used to provide information to veterinary surgeons (Lust, 2003).

In veterinary medicine there are a vast range of species and conditions that exist. Authorised veterinary medicinal products are not available to treat every condition in

different animal species. Available medicinal products may not be of the appropriate strength or formulation for animal patients (Mc Dowell et al., 2017). In exceptional circumstances, veterinary surgeons may use the prescribing cascade to use certain medicines off-label, and not adhere to the conditions of authorisation of the medicinal product to avoid unacceptable suffering of animal patients.[17] The cascade is a risk-based decision tree that is used when no suitable veterinary medicinal product is licensed for that treatment in the member state.[18] A specific prescribing sequence is observed. According to the cascade, the first choice are veterinary medicinal products licensed for the treatment of a different species or a different condition in the same species. Medicinal products intended for use in humans may be prescribed in the absence of any veterinary medicinal products that can be used. If no other product is available, the medicinal product can be prepared by extemporaneous preparation by authorised persons as prescribed by the veterinary surgeon (BSAVA, 2015).

1.9. Pharmacist Involvement in Veterinary Pharmacy Practice

Human and animal health, including their medical treatment, are closely related. Animal patients are diverse and may include companion animals, food-producing animals, captive animals and wildlife. Each group of animal patients have their unique health conditions but also share some health conditions with the human population. Pets, or animal companions, develop chronic conditions such as thyroid disorders, diabetes,

[17] Health Products Regulatory Authority (HPRA). Exceptional authorisation of veterinary medicines [Internet]. Ireland: HPRA; 2014 [cited 2020 Jun 06]. Available from: http://www.hpra.ie/homepage/veterinary/special-topics/exceptional-authorisation-of-veterinary-medicines#.

[18] Veterinary Medicines Directorate (VMD). The cascade: prescribing unauthorised medicines. Guidance for prescribing vets on the use of the cascade [Internet]. UK: VMD; 2015 [updated 2019 Jun 20; cited 2020 Jun 06]. Available from: https://www.gov.uk/guidance/the-cascade-prescribing-unauthorised-medicines.

osteoarthritis and cardiovascular diseases that are frequently seen in humans (McDowell et al., 2017).

Veterinary medicinal products are not available to treat every condition in different animal species. Medicinal products intended for use in humans are used off-label to treat disease states in animal patients. (Lust, 2004). Veterinary surgeons require medicinal products that are not available, are not of the appropriate strength or formulation for animal patients. Extemporaneous preparation and dispensing of medicinal products in pharmacies increase the accessibility to medication for animal patients (McDowell et al., 2017).

The pharmacist's responsibility to provide high-quality pharmaceutical care for both human and animal patients is the same (McDowell, 2011; O'Driscoll et al., 2014b). When dispensing medicinal products, pharmacists have a legal obligation to ensure that the medication prescribed, the dose, route of administration and frequency are suitable according to its intended use (McDowell et al., 2017). Pharmacists are uniquely positioned to assist clients in solving medication issues and to collaborate with veterinary surgeons to provide the best care for their mutual patients (O'Driscoll et al., 2014a; O'Driscoll et al., 2014b; Bennet et al., 2018).

1.10. Challenges for Veterinary Pharmacy Practice

Community pharmacists are providing services to pet owners by dispensing medicinal products for use in animals but pharmacists lack training in veterinary pharmacy (Ceresia et al., 2009; Davidson, 2019). Traditionally, curricula for pharmacy students, are centred around humans and their disease states. This challenges the pharmacist's knowledge on

aspects of veterinary pharmacy such as disease states affecting companion animals, pharmacotherapy options, posology and administration, adverse effects, drug information resources and client counselling (Lust, 2003; Lust, 2009; Miller and Sehgal, 2016).

Prescriptions for medicinal products for veterinary use present a challenge for pharmacists (Lust, 2004). Pharmacists dispensing veterinary prescriptions rely heavily on the veterinary surgeon for accurate and appropriate medication dosing and prescription checks may not be performed (O'Driscoll et al., 2015). In practice, pharmacists may be unaware of aspects associated with veterinary pharmacy such as regulatory and public health aspects (Ceresia et al., 2009). Doctor of Pharmacy curricula, and undergraduate pharmacy degrees may not provide training in veterinary physiology, disease states, pharmacology, pharmacokinetics, drug administration, adverse effects or counselling for diseases and pharmacotherapy (Adrian et al., 2014; Miller and Sehgal, 2016).

In the United States of America (USA), the Accreditation council for Pharmacy Education's Standards do not require veterinary pharmacy education as part of the curricula for the training of Doctor of Pharmacy (Young et al., 2018). A 2015 report indicated that few accredited Schools of Pharmacy within the USA offer courses or modules in veterinary pharmacy, clinical rotations or any other specialised opportunities with only 4%, of pharmacy students graduating in 2015 receiving training veterinary pharmacotherapy (Young et al., 2018; Davidson, 2019). Lack of training results in graduating pharmacists having limited knowledge, skills and exposure to veterinary pharmacy (Young et al., 2018).

A working knowledge of veterinary therapeutics is essential among pharmacists providing veterinary services. A lack of knowledge and confidence in veterinary pathophysiology, pharmacotherapy and legal aspects have been reported among pharmacists. This prevents pharmacists from getting involved in veterinary pharmacy (O'Driscoll et al., 2014a; Young et al., 2018). Pharmacists involved in veterinary pharmacy require an appreciation of veterinary products and must dispense medicinal products for animal use with the same diligence and attention given to human drugs (Ceresia et al., 2017).

1.11. Impact of Education and Training in Veterinary Pharmaceutical Sciences

The fundamental aim of pharmacy education is to provide students with the knowledge and skills to become pharmacists and, subsequently, to enable them to remain competent in their profession (Salter et al., 2014). It is challenging for educators of pharmacy to identify how best to prepare pharmacists to assist veterinary surgeons in providing pharmaceutical services to animals (Ceresia et al., 2009). From the perspective of clinical pharmacy, human medicine and veterinary medicine complement each other with pharmacists that are solely trained around human diseases uniquely positioned to provide education and serve veterinary surgeons and animal owners (Lust, 2009).

Lust in 2003, used an online platform for a continuing education course whereby pharmacists could access an electronic learning environment to obtain up-to-date information with respect to training in veterinary therapeutics, veterinary disease states and regulatory issues. The web-based design also included access to self-assessment quizzes and questionnaires. The effectiveness of this curriculum was assessed by measuring the knowledge, confidence and competencies using pre- and post-course

surveys. The study reported that this learning environment increased the knowledge skills and competencies in the field of veterinary therapeutics (Lust, 2003). Ceresia et al., in 2009, tried to delineate the educational and training need of traditional, community pharmacists who support the needs of the veterinary surgeons and those pharmacists who practice solely veterinary pharmacy.

Young et al., in 2018, authored a study which demonstrated the importance of veterinary pharmacy education to pharmacy graduates, to improve their ability to safely dispense medicinal products for use in animals. The authors strongly suggested the introduction of training modules in schools and through professional organisations to allow pharmacists to be able to answer questions related to medication, understand the differences in animal physiology and provide the appropriate drug information to support pet owners. Trained pharmacists may also serve as interprofessional collaborators with veterinary surgeons (Young et al., 2018).

There are different veterinary pharmacy education programmes, offered by different education institutions that offer training in veterinary pharmacy. Harper Adams University College in the UK offer different veterinary pharmacy programmes for different target audiences who are involved in the provision of animal health. These may include pharmacists, pharmacy technicians, pharmacy support staff and veterinary nurses. The postgraduate diploma in Veterinary pharmacy and the Masters in veterinary pharmacy that cover professional practice for veterinary pharmacy.[19]

[19] Harper Adams University. PgC / PgD / MSc Veterinary Pharmacy [Internet]. UK: Harper Adams University; 2020 [cited 2020 Jun 06]. Available from: https://www.harper-adams.ac.uk/courses/postgraduate/116/veterinary-pharmacy.

The University of Florida offers Continuing Pharmacy Education courses in Veterinary pharmacy for practising pharmacists. The aim is to prepare community pharmacists to meet legal counselling requirements, prevent or resolve drug-related problems and safely dispense medicinal products for use in animals. Education on veterinary disease states and medicinal products used to treat these conditions is also included.[20]

1.12. Rationale, Aims and Objectives

The health and medical treatment of humans and animals are closely linked. Pharmacists are uniquely positioned to counsel pet owners and collaborate with veterinary surgeons to improve animal care and access to safe and effective medicines. Pharmacist involvement in the veterinary sector is hindered by the lack of education and training in veterinary pharmaceutical sciences. Education and training on veterinary disease states, pharmacotherapeutic options and the regulation of veterinary medicinal products empowers pharmacists to become active participants in the different areas within the veterinary field.

The aim of the study is to develop regulatory policies and an academic framework in veterinary pharmaceutical sciences.

The objectives of the study are:

1. To develop a training programme for pharmacists in veterinary pharmaceutical sciences based on feedback generated by the dissemination of three self-administered questionnaires for veterinary surgeons, pharmacists, and pet owners.

[20] University of Florida (UF) College of Pharmacy. Veterinary pharmacy practice for practicing pharmacists [Internet]. USA: UF; [cited 2020 Jun 06]. Available from: https://cpe.pharmacy.ufl.edu/courses-04-24-2019/certificate-courses/veterinary-pharmacy-for-practicing-pharmacists/.

2. To analyse the systems and resources of different EU competent authorities that regulate veterinary medicines by means of a self-administered questionnaire for the different National Competent Authorities within the EEA that regulate veterinary medicinal products.

3. To propose the framework for a support office within an entity specialised in human medicinal products to extend its services to veterinary medicinal products with respect to assessment of veterinary medicinal products and medicines information.

Chapter 2

Methodology

This chapter outlines the methodological framework adopted to fulfil the research objectives.

The methodology is divided into two parts:

Part I presents the process undertaken to evaluate the perception of the role of the pharmacist and the contribution towards the treatment of companion animals and animal care. Current challenges and barriers with respect to access to medicinal products and good animal care are also identified in this section. The process undertaken in the development and validation of the training programme in veterinary pharmaceutical sciences for pharmacists is provided. The process is divided into two phases. Phase I includes the development, validation and dissemination of three separate questionnaires to veterinary surgeons, pharmacists and pet owners. In Phase II the training programme for pharmacists in veterinary pharmaceutical sciences is developed and validated.

Part II presents the process undertaken to identify the resources required for a regulatory entity specialised in human medicinal products to extend its services to veterinary medicinal products with respect to assessment of veterinary medicinal products, medicines intelligence, access and information. A proposal for the establishment of a support office for veterinary medicinal products within an entity responsible for the regulation of human medicinal products was developed. The main responsibilities of the unit are the assessment of veterinary medicinal products, medicines information and access.

2.1. Approvals and consent

Approval by the University of Malta Faculty of Medicine and Surgery Research Ethics Committee (FREC) was granted for the proposed protocol, prior to study initiation.

2.2. Part I (Phase I): The Role of the Pharmacist in Veterinary Pharmacy: Challenges and Barriers

Three separate questionnaires were developed for different target audiences; veterinary surgeons, pharmacists and pet owners. The questionnaire for veterinary surgeons was entitled 'The veterinary surgeon's perception of the role of the pharmacist, challenges and barriers regarding access to medicinal products and animal care' (VSP-Q). The questionnaire intended for pharmacists was entitled 'The perception of the role of the pharmacist, challenges and barriers regarding access to medicinal products and animal care' (PHP-Q). The questionnaire for pet owners was entitled 'The pet owner's perception of the role of the pharmacist, challenges and barriers regarding access to medicinal products and animal care' (POP-Q).

Questions in the VSP-Q, PHP-Q and POP-Q were adapted from Soler (2012), Bennett et al. (2018). Original questions were also developed by the researcher for the purpose of this study. Questions sought to identify the perception of the role of pharmacists specialised in human medicines within the veterinary pharmaceutical sector. VSP-Q and PHP-Q also assessed whether there is the potential of interdisciplinary collaboration to provide the best care for animal companions. POP-Q was designed to obtain information about the nature of the medication given to pets and the challenges they face when administering the medication. Pet owners' perception of the role of the community pharmacist was also assessed.

2.2.1. Design and Structure of VSP-Q, PHP-Q and POP-Q Questionnaires

The questionnaires used a combination of close-ended and open-ended question styles. The close-ended questions/statements were multiple-choice and checklist type

questions/statements. The multiple choice questions enabled respondents to choose the most suitable answer from the list provided, a 5-point Likert-scale being a psychometric scale where respondents indicate their choice at the most appropriate point on a scale (Taylor-Powell, 1998) and categorical, in which each respondent's opinion has to fall into a particular category. The Likert scales used measured the level of agreement and ranged from 1-5, anchored by 5 which represented the highest score. Other Likert scales measured frequency and ranged from 1-5, anchored by 5 which represented the highest frequency. Check-list type statements/ questions were used where one or more responses were required. An 'Other' option was added to each check-list type question/statement to include any responses that were not given as options.

Close-ended questions were chosen to obtain more accurate results, to yield higher response rates, to provide more solid data since open-ended questions produce missing data and to make it easier to analyse statistically (Reja et al., 2003; Fink, 2009). A disadvantage to the use of close-ended questions is the potential for bias since responses available would be limited (Keeney et al, 2001).

Structure of VSP-Q

The VSP-Q was divided into three different sections as follows:

i. Section A: Demographic Data

   Demographic information included the veterinary surgeon's gender, locality of practice and age.

ii. Section B: Challenges of access to medicine

   This section dealt with identifying the challenges of access to medicine and consisted of a total of twelve questions. In this section veterinary surgeons were

asked about their current practices, challenges encountered when deciding on treatment options for their patients, motivations for prescribing human medicinal products and the challenges the pet owners face when giving medication to their pets.

iii. Section C: Perception of the pharmacist and pharmacy services

This section dealt with identifying the perception of the pharmacist and pharmacy services and consisted of fourteen statements using a Likert scale and two check-list type questions. Questions in this section were aimed at seeking information about the veterinary surgeon's perception of the pharmacists in relation to the pharmacist's knowledge and skill in caring for animal patients, ability to safely dispense and provide advice for animal prescriptions and possibility of collaboration to improve animal care. Veterinary surgeons were asked whether pharmacists should be trained in veterinary pharmaceutical sciences. The final question in this section asked veterinary surgeons about any services they would like community pharmacies or pharmacists to offer.

Structure of PHP-Q

The PHP-Q was divided into four different sections as follows:

i. Section A: Demographic Data

Demographic information included the pharmacist's gender, age and identification of the sectors the pharmacist worked in within the past five years.

ii. Section B: Current practices

This section dealt with identifying current practices of pharmacists who had ever worked, or were currently working in a community pharmacy and consisted of eight questions, four multiple choice questions, two check-list type questions and

two open-ended questions. In this section pharmacists were asked about trends of dispensing of medicinal products for use in animals and the type of extemporaneous preparations performed. Pharmacists were asked about the resources they used for the provision of information when counselling patients.

iii. Section C: Challenges of access to medicines

In this section pharmacists were asked whether they were aware of the challenges pet owners encounter when administering medication to their pets and the challenges veterinary surgeons encounter when deciding on treatment options. The section consisted of six questions, three multiple choice, and three check-list type questions.

iv. Section D: Perception of the pharmacist and pharmacy services

This section was structured as described for Section C for the VHP-Q.

Structure of POP-Q

The POP-Q was divided into three different sections as follows:

i. Section A: Demographic Data

This section included statements requesting the gender, age, locality of residence and level of education of pet owners.

ii. Section B: Challenges of access to medicine

This section dealt with gathering information on the type of pets, the age of the pets, any medical conditions the pets suffered and whether their pet had been prescribed any medication. The section also gathered information about the nature of the pets' medication and identified the challenges pet owners faced when giving medication to their pets. Pet owners were also asked how often they asked a pharmacist for advice regarding their pet. The section consisted of thirteen questions, seven multiple choice questions, four check-list questions and two open-ended questions.

iii. Section C: Perception of the pharmacist and pharmacy services

The structure of this section is based on that described for VSP-Q. This section dealt with identifying the perception of the pharmacist and pharmacy services and consisted of a total of twelve questions, ten likert-scale, one multiple choice statement and one checklist type question. Questions asking whether pet owners would be willing to ask the pharmacist for advice about their pet and medication use in animals were included.

2.2.2. Determination of Content Validity Index

The Content Validity Index (CVI) was used to validate the three questionnaires (VSP-Q, PHP-Q and POP-Q).

Pilot testing

A pilot testing phase to verify the feasibility of the questionnaires were carried out. The pilot testing was performed on 25 respondents chosen at random. The respondents were asked to rate their opinion on the overall questionnaire after completing it. The comments were taken into consideration for the final version of the questionnaires prior to its validation.

Selection of Validation Panel Members

A total of 6 experts, 3 Maltese and 3 foreigners were selected to participate. They were contacted by means of electronic mail and invited to participate. Each participant was approached by the researcher and the aims of the validation study were clearly outlined. The experts consisted of (i) *two veterinary surgeons*:- both practicing in a private veterinary clinic (Northern District); (ii) *three pharmacists*:- one community pharmacist,

one pharmacist working in regulatory affairs and one pharmacist working in academia and research and (iii) *one linguist*.

Content validation procedure

A 5-point rating scale was used during the validation, as recommeded by Almenasreh et al. (2019) to enable the rater to be unsure or neutral. The 5-point likert scale ranged from 1 (not relevant, not clear and not well-structured) to 5 (very relevant, very clear and very well-structured).

The content validation document was prepared with instructions to ensure that the expert panel had a clear understanding of what was expected of them. Each member of the validation panel was given a validation document both as an electronic and printed format. The experts were requested to critically review each question and provide a score for each item. They were also asked to provide any comments to improve relevance, clarity and structure of the questions.

For each domain the CVI was calculated for each item in the questionnaire (I-CVI) and the average CVI of the whole instrument (Ave-CVI) were computed. The I-CVI represents the proportion of the experts from the panel rating items for a domain as '4' or '5'. The Ave-CVI is the average proportion of items rated as '4' or '5' (valid) across the various experts (Almanasreh et al., 2019). The Ave-CVI was calculated by calculating the average CVI across the items by summing the I-CVIs and dividing them by the number of items.

Item-CVI (I-CVI) was used to guide in revising, deleting or substituting any items. The I-CVI threshold for revision or omission was taken as 0.83 at a 0.05 level of significance using the matrix proposed by Lynn (1986). Where the I-CVI was < 0.83 items were deleted,

modified or added taking into account any comments provided by the expert validation panel. The amended questionnaire was submitted for Round 2.

2.2.3. Reliability Testing

The reliability of a questionnaire is the extent to which it produces stable and consistent results (Taherdoost, 2016). The reliability of the three questionnaires was assessed using the test-retest approach by administering the same questionnaire to ten members in each target audience two weeks apart.

Statistical tests used to determine reliability included the Kendall Tau test for ordinal scales and the Kappa values for nominal scales. The data was analysed using Statistical Package for the Social Sciences (SPSS) version 24 (IBM Corporation, New York, USA). For both tests the null hypothesis was accepted if the p value exceeded the 0.05 level of significance and was rejected if the p value was less than the 0.05 criterion. The null hypothesis specifies that there is poor intra-subject reliability between responses. The alternative hypothesis specifies that there is satisfactory intra-subject reliability between responses.

2.2.4. Dissemination of VSP-Q, VHP-Q and POP-Q

The questionnaire for veterinary surgeons (VSP-Q) was disseminated through the veterinary surgeons council. The validated questionnaire was sent to, and approved by, the veterinary surgeons council prior to dissemination. The veterinary surgeons council disseminated the questionnaire to veterinary surgeons registered with the council. One hundred forty-nine veterinary surgeons are registered with the veterinary surgeons

council. The questionnaires for pharmacists and pet owners were disseminated via social media platforms reaching a population of 860 and 80,500 members respectively.

2.2.5. Data Analysis: VSP-Q, VHP-Q and POP-Q

Data was coded and analysed using the Statistical Package for the Social Sciences (SPSS) version 24 (IBM Corporation, New York, USA). The Chi square test was used to assess the association between two categorical variables. The null hypothesis states that there is no association between the two variables while the alternative hypothesis states that there is a significant association between the two variables. For all three tests, the null hypothesis was accepted if the p value exceeded the 0.05 level of significance and was rejected if the p value was less than the 0.05 criterion.

2.3. Part I (Phase II): Training Programme in Veterinary Pharmaceutical Sciences

The data collected from the questionnaires was used identify current gaps, barriers and challenges faced by veterinary surgeons, pharmacists and pet owners. The data was taken into account during the design of the training programme for pharmacists in veterinary pharmaceutical sciences.

2.3.1. Design of the Training Programme for Pharmacists in Veterinary Pharmaceutical Sciences

A literature search was conducted on pharmacy-education related journals including the *American Journal of Pharmaceutical Education, Pharmacy Education, Currents in Pharmacy Teaching and Learning* and other published literature that describe studies centred around integrating different veterinary pharmacy training programmes into

different settings. A search was conducted to identify institutions, such as Harper Adams University in the United Kingdom, The College of Veterinary Medicine, North Carolina State University in the United States of America (USA), College of Veterinary Medicine, Purdue University in the USA and College of Veterinary Medicine, University of Florida in the USA that offer different training programmes in veterinary pharmacy.

Information from these websites together with published training material in the field of veterinary pharmacy and the data obtained from VSP-Q, VHP-Q and POP-Q were used to identify the main areas of the training programme. For each of the main areas identified, the researcher developed a description of the content, a number of aims and learning outcomes. The learning outcomes were divided into knowledge and understanding, and skills.

2.3.2. Validation of the Training Programme

The training programme for pharmacists was validated using a two-round modified e-Delphi method. The Delphi technique is a widely used and accepted method for collecting feedback from experts (Ravensbergen et al., 2019). The e-Delphi technique is a variation of the classical technique that employs the use of on-line communication (Meshkat et al., 2014; Msibi et al., 2018).

The Delphi technique is an extensively used and accepted method for collecting feedback from respondents within their field of expertise (Hsu and Sandford, 2007; Petry et al, 2007; Sermeus et al, 2009; Elliott et al, 2011; Boulkedid et al, 2011; Soon et al, 2012; Créange and Careyron, 2013).

Characteristics of the Delphi technique

The Delphi technique involves communication with a group of experts. It is a means of seeking expert opinion through a systematic, multistage series of questionnaires with the aim of transforming opinions into consensus (Covvey and Ryan, 2018). The advantage of the e-Delphi technique is that it allows the experts involved the liberty to participate at their own pace at their preferred time (Meshkat et al., 2014; Msibi et al., 2018).

The Delphi method is useful when there is little or no definitive evidence about issues of interest, and where opinion is important (Meshkat et al., 2014). The Delphi method has been applied in varied situations such as examining historical events, academic research and curriculum development (Sitlington and Coetzer, 2014). The use of the e-Delphi technique allows participants to remain anonymous. Experts are able to express their opinions and views without being influenced by other participants, and also protects the participants when their opinions are not in agreement with others (Msibi, 2019).

Delphi panels can range between 7 experts (Chu and Hwang, 2008) to 115 experts (Grundy and Ghazi, 2009). Participants can be either homogeneous or heterogeneous in terms of age, nationality, knowledge, qualifications, expertise or position (Day and Bobeva, 2005). The expertise of Delphi participants affects outcome quality and should be chosen wisely (Gordon, 1994).

The number of sequenital questionnaires, called ‘rounds’, is agreed at the start of a procedure and usually ranges from 2 to 4 and can vary between 2 and 10 (Day and Bobeva, 2005; Iqbal and Pipon-Young, 2009; Meshkat et al., 2014). Ideally the same

expert panel is engaged throughout the process (Day and Bobeva, 2005; Iqbal and Pipon-Young, 2009).

Selection of Experts for Validation of the training programme

A total of eight individuals with different areas of expertise were invited to form part of a panel for the Delphi- based validation exercise. Selection of experts for the e-Delphi study was made through personal contacts of the researcher and experts nominated by others. Participants were not selected randomly, so representativeness was not assured.

A total of 8 experts, 6 Maltese and 2 foreigners were selected to participate. They were contacted by means of electronic mail and invited to participate. Each participant was approached by the researcher and the aims of the validation study were clearly outlined. The heterogeneous group of 8 experts, six female and two male, consisted of (i) *two veterinary surgeons*:- both practicing in a private veterinary clinic (Northern District); (ii) *four pharmacists*:- one community pharmacist, one pharmacist working in regulatory affairs and two pharmacists working in academia and research; (iii) *one academic* specialised in health informatics and data science and (iv) *one linguist*.

e-Delphi Method

The goal of the e-Delphi method was to establish consensus on a list of potential aims and learning outcomes for each of the main areas of the proposed training programme. The platform used to design and disseminate the questionnaires was a commercially-available online survey tool 'Google Forms'.

The first round of the Delphi validation consisted of a potential list of aims and learning outcomes for the three main areas of the proposed training programme. These included veterinary disease states, veterinary pharmacotherapy and regulation of veterinary medicinal products. Learning outcomes were divided into 'Knowledge and Understanding' and 'Skills'. The proposed list consisted of 140 items divided as follows (Table 2.1):

Table 2.1 The number of aims and learning outcomes in each of the proposed areas of the training programme for pharmacists (N = 140)

Area	Aims	Learning Outcomes	
		Knowledge and Understanding	Skills
Veterinary Disease states	4	30	12
Veterinary Pharmacotherapy	9	49	20
Regulation of veterinary medicinal products	6	8	2

In Delphi Round I a clear explanation of the goals was provided, including instructions on how to fill in the questionnaire, the seven-day timeline for the answers to be provdied and contact details. Each respondent was requested to rate the aims and learning outcomes on a five-point Likert scale of weighted importance. Statements which were deemed to be not at all important were to be given a rating of 1, those that were not important were to be given a 2 and a neutral opinion was given a 3. Statements which were, in the expert's opinion, very important or extremely important were given a rating of 4 and 5 respectively. Participants were given the option to provide additional comments.

The consensus threshold was established a priori to avoid post-hoc bias of results. Consensus for inclusion of the aims and learning outcomes was reached if greater than or equal to 80% of the experts have rated statements as “Important” or “Very important”. Findings from a systematic review by Diamond et al., (2014) indicated that 75% was the median threshold to define consensus. Covvey and Ryan (2018) suggested that 75% consensus was commonly employed in Round I. In their study, the consensus threshold was increased with each successive round; to 80% in Round II and 85% for Round III. The consensus level in this study was set at 80%, equivalent to that suggested for Round II since two rounds of Delphi were performed.

The aims and learning outcomes of the training programme, which included suggestions arising from Delphi Round I, such as omissions and re-wording were submitted for Delphi Round II. The same individuals participating in Round I were asked to participate in Delphi round II which was conducted using the same method as Round I.

2.4. Part II: Identification of the resources required for a regulatory entity specialised in human medicinal products to extend its services to veterinary medicinal products.

Part II describes the process undertaken to propose the setup of a support office within a regulatory entity specialised in human medicines that extends its services to veterinary medicinal products. Services that were considered included assessment of veterinary medicinal products and medicines information, intelligence and access. The data obtained from analyses of the regulatory framework and the questionnaire for the identification of resources required for a regulatory entity specialised in human medicinal product to extend its services to veterinary medicinal products were taken into consideration for the proposal.

2.4.1. Analysis of the Regulatory Framework

Regulations governing veterinary medicinal products were identified. EU law and National law were compared. The dossier requirements for veterinary medicinal products and human medicinal products were analysed.

Analysis of the regulations governing veterinary medicinal products

A gap analysis is a method for identifying elements that are not represented or underrepresented in an existing framework or system (Jennings, 2000). An analysis for the laws governing veterinary medicinal products was performed. Veterinary medicinal products fall under Directive 2001/82/EC which was transposed into subsidiary legislation S.L.437.47 of the Laws of Malta (The European Parliament and the Council of the European Union, 2001a).[21] Regulation (EU) 2019/6 will come into force in 2022 and will repeal Directive 2001/82/EC (The European Parliament and the Council of the European Union, 2019). Regulation (EU) 2019/6 was included in the analyses. The analysis of the regulatory framework was carried out by comparing Directive 2001/82/EC with S.L. 437.47 and Regulation (EU) 2019/6 with Directive 2001/82/EC.

Directive 2001/82/EC was chosen as the reference. The comparator was S.L. 437.47. The analysis was carried out using Microsoft Excel®. All the articles, paragraphs and sub-paragraphs of Directive 2001/82/EC were inputted into Microsoft Excel with each paragraph in separate cells. The corresponding text was identified, and the text was inputted next to its counterpart. This process was repeated for all the paragraphs and sub-paragraphs. Upon completion of the procedure, the data obtained was analysed. The

[21] Ministry for Justice, Culture and Local Government. Subsidiary Legislation 437.47 Veterinary Medicinal Products Regulations [Internet] Malta: The Ministry 2004: 1-103 [cited 2020 Jun 23]. Available from: http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10983&l=1.

procedure was repeated using Regulation (EU) 2019/6 as the reference and Directive 2001/82/EC as the comparator.

Dossier Requirements

Annex I of Directive 2001/82/EC and Annex I of 2001/83/EC represent dossier requirements for veterinary medicinal products and human medicinal products respectively (The European Parliament and the Council of the European Union, 2001a; The European Parliament and the Council of the European Union, 2001b). The requirements for veterinary medicinal products were compared to requirements for human medicinal products to identify similarities and differences. Dossier requirements as specified in Annex II of Regulation (EU) 2019/6 and Annex I of Directive 2001/82/EC were also compared to identify any differences in dossier requirements included in the new regulation for veterinary medicinal products (The European Parliament and the Council of the European Union, 2001a; The European Parliament and the Council of the European Union, 2019).

2.4.2. National Competent Authorities within the European Economic Area

The European Medicines Agency provides a list of all the National Competent Authorities that regulate medicinal products within the EEA. Two lists corresponding to the NCAs regulating human[22] and veterinary[23] medicinal products were analysed by the researcher to identify which NCAs within the EEA regulate both human and veterinary medicinal products.

[22] European Medicines Agency (EMA). National competent authorities (human) [Internet]. The Netherlands: European Medicines Agency; 2020 [cited 2020 May 16]. Available from: https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human.

[23] European Medicines Agency (EMA). National competent authorities (veterinary) [Internet]. The Netherlands: European Medicines Agency; 2020 [cited 2020 May 16]. Available from: https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-veterinary.

2.4.3. Identification of Resources of Different National Competent Authorities

The questionnaire for National Competent Authorities entitled "Identification of resources of different EU National Competent Authorities that regulate veterinary medicinal products " (NCA-Q) was developed to identify the different resources of NCAs that regulate veterinary medicinal products in different member states.

The questionnaires used a combination of close-ended question styles and open-ended questions. The close-ended questions were multiple-choice and check-list type questions. Open-ended questions were used where a rationale behind a specific response was required and where the respondent was asked to describe a sytem or process.

The NCA-Q consisted of four sections:

i. Section A: General information

   This section was intended to collect general information about the NCAs that regulate veterinary medicinal products and consisted of ten questions, four multiple choice, four checklist-type questions and two open-ended questions. In this section, respondents were asked which areas fall under the remit of the NCA and what services does the NCA offer. This section gathers data pertaining to training of personnel offering services in the veterinary pharmaceutical sector.

ii. Section B: Assessment of veterinary medicinal products

   This section dealt with identifying the resources different NCAs had allocated towards the assessment of veterinary medicinal products. Questions were targeted to obtain information regarding the different types of assessments that are carried out for veterinary medicinal products, for which procedures, who performs assessments and any training given to the assessors to be able to carry out these

tasks. This section consisted of twelve sections, five check-list type questions, four multiple choice and three open-ended questions.

iii. Section C: Medicines information, access and intelligence

This section dealt with identifying the resources of different NCAs with respect to medicines information, intelligence and access. Respondents were asked to briefly describe the role of the NCA within this sector and any qualification requirements and training needs for those giving this service. This section consisted of seven questions, three multiple choice questions, three open-ended questions and one check-list type question.

iv. Section D: Collaboration with NCAs

The aim of this section was to identify whether the NCA regulating veterinary medicines collaborates with different NCAs. Respondents were asked to identify how and in which areas do the different NCAs cooperate or collaborate. The section consisted of three questions, two check-list type questions and one multiple choice.

2.4.4. Determination of Content Validity Index, Dissemination and Data Analysis of the Questionnaire for National Competent Authorities.

The NCA-Q was validated as described in section 2.2.1.2 using the same expert panel.

The questionnaire was disseminated to thirty-five National Competent Authorities that regulate veterinary medicinal products within the EEA. The contact email address for each NCA was retrieved from the EMA website.

The data was analysed as described in section 2.2.1.5.

2.4.5. Proposal for Veterinary Medicine Support Office

A proposal for a support office within a regulatory entity specialised in human medicines that extends its services to veterinary medicinal products was developed (Appendix 11) taking into account the outcomes of the analyses of the regulatory framework and data from the NCA-Q. Services that were considered included assessments of veterinary medicinal products and medicines information.

Chapter 3

Results

The results chapter reports on the following:

- The perception of the role of the pharmacist, challenges and barriers regarding access to medicinal products and animal care.
- The training programme for pharmacists in veterinary pharmaceutical sciences
- The identification of resources required for a regulatory entity specialised in human medicinal products to extend its services to veterinary medicinal products.
- A proposal for a support office within a regulatory entity specialised in human medicine to extend its services to veterinary medicinal products.

3.1. Part I (Phase I): The Role of the Pharmacist in Veterinary Pharmacy: Challenges and Barriers

The results reported in Phase 1 include the perception of the role of the pharmacist in animal care as reported by veterinary surgeons, pharmacists and pet owners.

3.1.1. Validation, Reliability Testing and Piloting of VSP-Q, PHP-Q and POP-Q

Six validation members completed both rounds of the validation process of the questionnaires by rating the questions proposed for the three domains of relevance, clarity and structure and layout (Appendix 2).

Validation: VSP-Q

In Round I, eleven questions or statements (22%) obtained an I-CVI below the 0.83 threshold and were flagged for omission or revision. One of the questions was in Section A, 3 in Section B and 3 in Section C. Thirteen questions (34%) obtained an I-CVI at the required threshold but additional comments were provided. Feedback from the expert validation panel was deemed important and comments were incorporated (Appendix 4).

Ave-CVI outputs were calculated at 0.95, 0.93 and 0.94 for the validation domains of relevance, clarity, and structure and layout respectively for VSP-Q. This further supports the robustness of the questionnaire.

Following modifications in Round I, all the questions or statements obtained an I-CVI of 1.00 and Ave-CVI of 1.00 in Round II. These values confirmed that VSP-Q was validated.

Validation: PHP-Q

Three questions or statements (10%), obtained an I-CVI below the 0.83 threshold and were flagged for omission or revision. Two of these questions pertained to Section A of the questionnaire and one pertained to Section B. Three questions (10%) obtained an I-CVI at the required threshold but additional comments were provided. Feedback from the expert validation panel was deemed important and comments were incorporated (Appendix 4). Ave-CVI outputs were calculated at 0.98, 0.98 and 0.99 for the validation domains of relevance, clarity, and structure and layout respectively for PHP-Q, further supporting the robustness of the questionnaire.

Following modifications in Round I, all the questions or statements obtained an I-CVI of 1.00 and Ave-CVI of 1.00 in Round II, confirming that PHP-Q was validated.

Validation: POP-Q

Four questions or statements (14%) obtained an I-CVI below the 0.83 threshold and were flagged for omission or revision. Two questions were in Section B and 2 in Section C. Eleven questions or statements (38%) obtained an I-CVI at the required threshold but

additional comments were provided. Feedback from the expert validation panel was deemed important and the comments were incorporated (Appendix 4). Ave-CVI outputs were calculated at 0.94, 0.94 and 0.93 for the validation domains of relevance, clarity, and structure and layout respectively for the questionnaire for veterinary surgeons.

The results were computed in the same manner as for round 1 for the three different questionnaires. All the questions or statements obtained an I-CVI of 1.00 and Ave-CVI of 1.00. The values satisfy the criteria and POP-Q was considered validated and suitable for dissemination. VSP-Q, PHP-Q and POP-Q can be found in Appendix 5.

Reliability

Ten members completed the two rounds of reliability testing for the validated VSP-Q, PHP-Q and POP-Q. Intra-subject reliability was upheld across the sections of the questionnaires.

3.1.2. The veterinary surgeon's perception of the role of the pharmacist, challenges and barriers regarding access to medicinal products and animal care

One hundred forty-nine veterinary surgeons were registered with the Veterinary Surgeons Council. Fourteen percent (n=21) of the registered veterinary surgeons compiled the questionnaire.

Sixty-two percent (n = 13) of respondents were male and 38 % (n = 8) were female. Forty-three percent (n = 9) of the veterinary surgeons were aged between 30 and 39 years, 28% (n=6) between 18 and 29 years, 14% (n = 3) between 40 and 49 years, 10% (n = 2) between 50 and 59 years, and 5% (n = 1) aged over 70 years.

Thirty-three percent (n = 7) had been practising as a veterinary surgeon for more than 10 years. Twenty-four percent (n = 5) had been practicing between 6 and 10 years and another 24% (n = 5) for less than 1 year. Nineteen percent (n = 4) had been practicing as a veterinary surgeon between 1 and 5 years.

The localities of practice of the veterinary surgeons were assigned to the Local Administrative Units (LAU) as specified by the National Statistics Office (NSO). Twenty-four percent (n = 5) practice their profession in the Northern district. The Southern Harbour and Northern Harbour districts each have 14% (n = 3) of the practicing veterinary surgeons. Ten percent (n = 2) of the veterinary surgeons practice in the Western district. None of the veterinary surgeons practice in the South Eastern Harbour district. Thirty-eight percent (n = 8) indicated 'Other' as their locality of practice. Responses for 'Other' included Malta, none and mobile.

Veterinary surgeons were asked to estimate the percentage of their patients that fall under the following categories: (1) small Animals, (2) large animals, (3) exotic species, (4) avian species and (5) other. Twenty-nine percent (n = 6) of veterinary surgeons indicated that small animals comprise more than 90% of the total patients. Ten percent of veterinary surgeons (n = 2) indicated that large animals comprise more than 90% of their patient load. Figure 3.1 shows how the veterinary surgeons estimate the percentage of their patients falling under these categories.

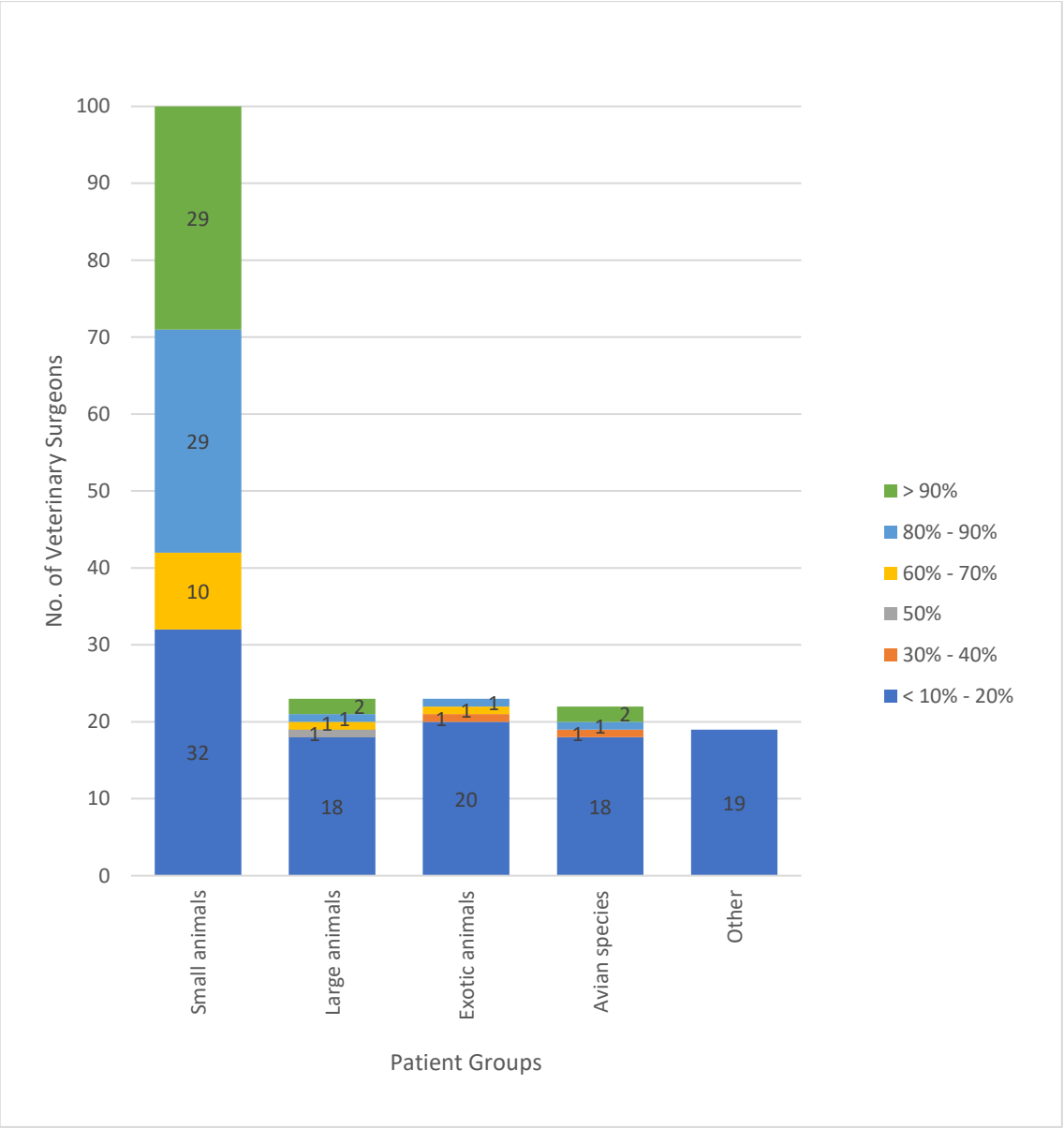

Figure 3.1: Animal patients classified into different patient groups (N = 21)

Sixty-one percent (n = 13) of the veterinary surgeons perform surgical procedures while nineteen percent (n = 4) do not. Ten percent (n = 2) do not perform surgical procedures anymore and 10% (n = 2) do not currently perform surgical procedures but are considering starting. Soft tissue surgery is the most common type of surgery performed, with 76% (n = 16) of the veterinary surgeons indicating that they perform this type of surgery. Dental procedures are performed by 38% (n = 8) of the veterinary surgeons and

orthopaedic and ophthalmic procedures are each performed by 29% (n = 6) of veterinary surgeons.

Seventy-six percent (n = 16) of veterinary surgeons do not dispense medication against another veterinary surgeon's prescription. Seventy-six percent (n = 16) do not perform compounding, 19% (n = 4) perform compounding and 5% (n = 1) do not offer this service anymore. Fourteen percent (n = 3) of the veterinary surgeons indicated that they perform compounding to make combination medications. Individualised medication strength/dose and individualised dosage forms were performed by 5% (n = 1) of veterinary surgeons. Where the service of compounding was offered, 29% (n = 6) indicated that the compounding was performed by the veterinary surgeon. Ten percent (n = 2) indicated that it was the pharmacist who performed compounding and 5% (n = 1) indicated that compounding was performed by a veterinary technician.

Pet owners face multiple challenges when giving medications to their pets as perceived by veterinary surgeons. Fifty-two percent (n = 11) of the veterinary surgeons indicated that the most challenging factor pet owners face is that their pet would not eat or swallow the medication. Thirty-three percent (n = 7) rated compliance to the treatment regimen as being the most challenging. The least challenging factor that pet owners face, according to 52% (n = 11) of the veterinary surgeons, is that the medication smelled bad to them. Individual ratings of the different challenges can be found in Figure 3.2. Each statement was rated from 1 (least challenging) to 5 (most challenging).

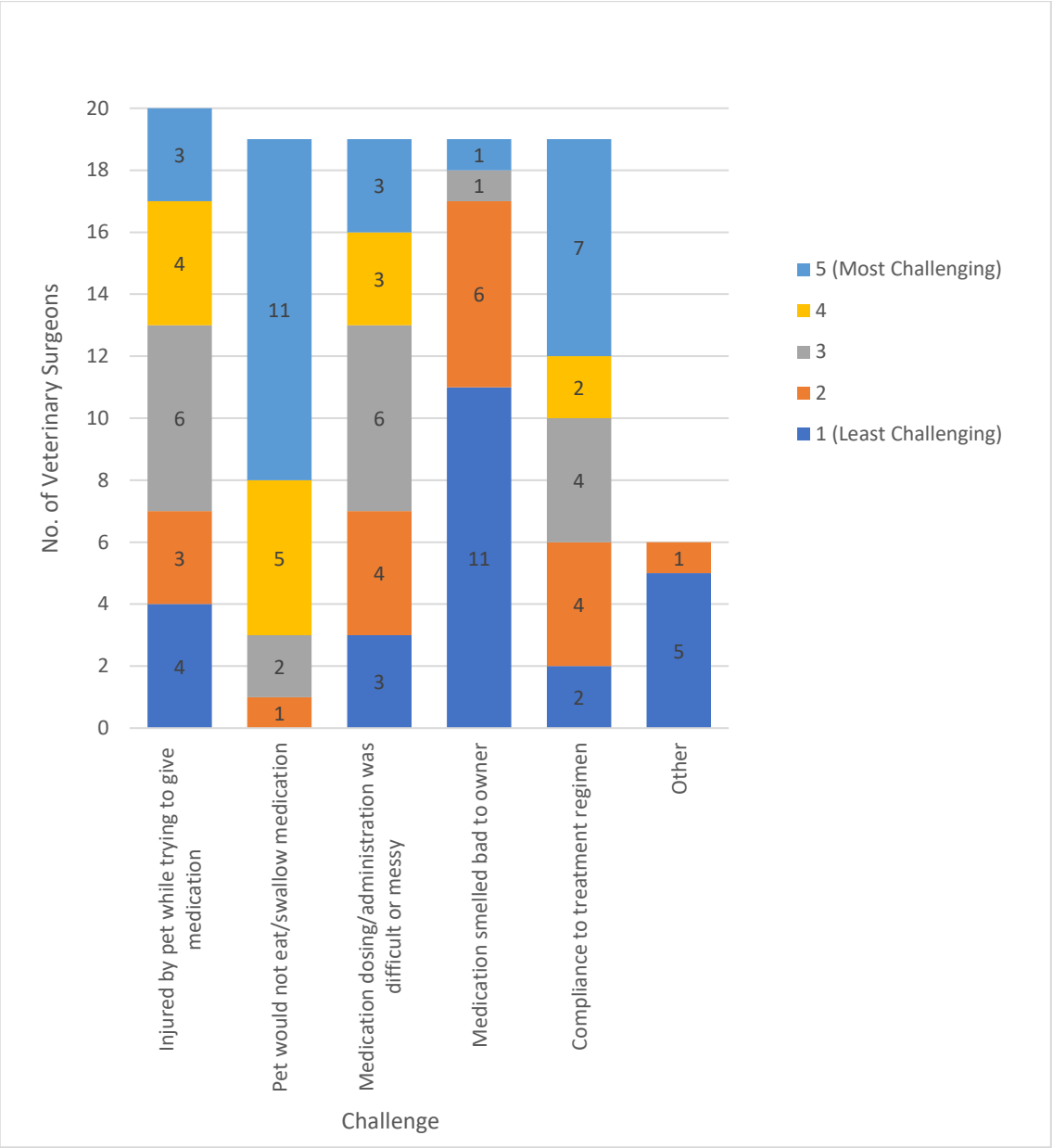

Figure 3.2: Challenges pet owners face when administering medication (N = 21)

Veterinary surgeons must take into consideration a number of factors when deciding on treatment options for their patients. Results show that the most challenging factors that influence their treatment choice is that owners were not able to administer the formulation available and that the dosage form available was not appropriate for animal administration. This finding was reported by 38% (n = 8) and 33% (n = 7) of veterinary surgeons respectively. Forty-three percent (n = 9) of veterinary surgeons reported that

another challenge is that the medicine required is not available in the community. Individual ratings of the different challenges can be found in Figure 3.3. Each statement was rated from 1 (least challenging) to 5 (most challenging).

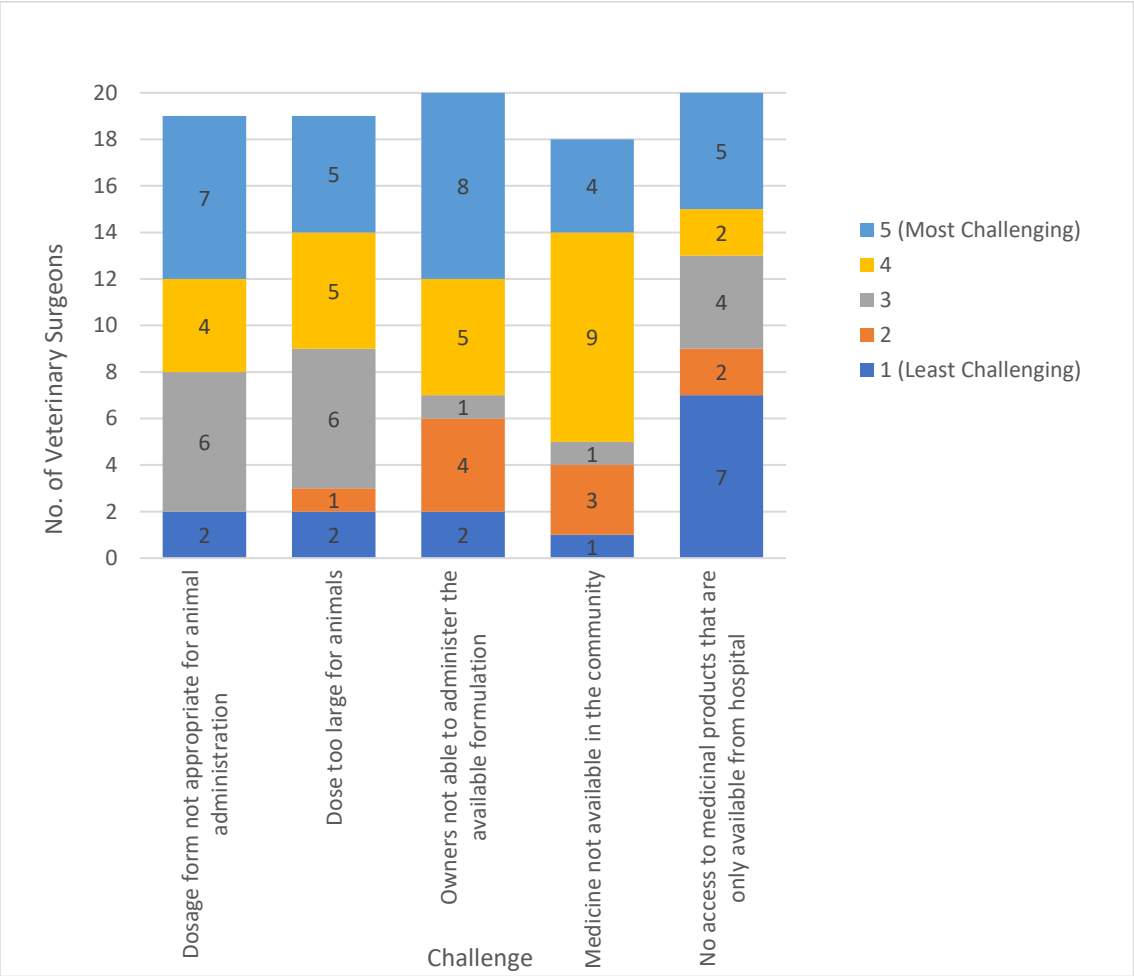

Figure 3 3 Challenges veterinary surgeons face when deciding on treatment options (N=21)

Veterinary surgeons prescribe human medicines for use in animals. Eighty percent (n = 17) of the veterinary surgeons stated that the main motivation behind the prescription of human medicines for use in animals is that the veterinary medicinal required is not available. Forty-eight percent (n = 10) indicated that they prescribe human medicines since the veterinary equivalent does not exist. Fourteen percent (n = 3) prescribe human medicines for use in animals as it is problematic for pet owners to access a clinic or

veterinary pharmacy. Another 14% (n = 3) stated that they do not prescribe human medicines for use in animals.

Veterinary surgeons were asked how often they prescribe human medicines for use in animals. According to 43% (n = 9) of veterinary surgeons, they prescribe human medicines on a weekly basis and 24% (n = 5) on a monthly basis. Figure 3.4 shows the frequency with which veterinary surgeons prescribe human medicines.

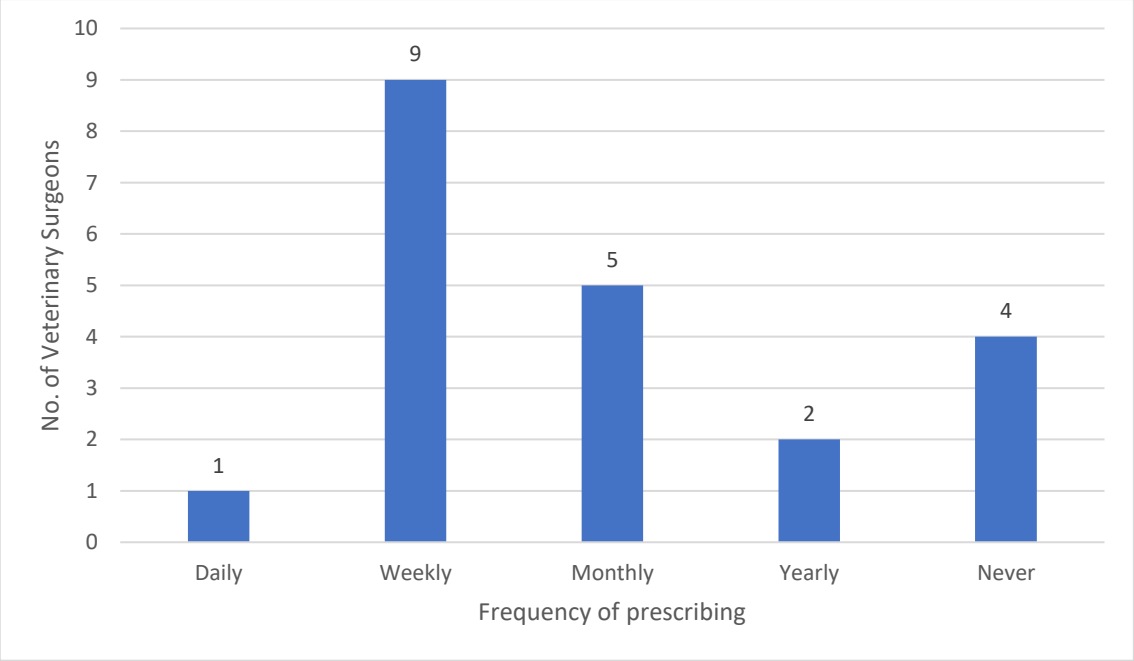

Figure 3.4: Frequency with which veterinary surgeons prescribe human medicines (N=21)

Fifty-two percent (n = 11) of the veterinary surgeons neither agreed nor disagreed when asked whether veterinary surgeons are increasingly prescribing human medicines for use in animals. Twenty-eight percent (n = 6) disagreed with this statement and 10% (n = 2) agreed. Five percent (n = 1) strongly agreed and 5% (n = 1) strongly disagreed with this statement.

Veterinary surgeons were presented with statements to gather data regarding their perception of the pharmacist and the pharmacist's role in caring for animal patients. Forty-three percent (n=9) of the veterinary surgeons neither agreed nor disagreed that pharmacists possess competence in caring for veterinary patients. Thirty-three percent (n=7) agreed and 19% (n=4) strongly agreed that the pharmacist does not possess competence.

Thirty-eight percent (n = 8) of the veterinary surgeons disagreed, and 29% (n = 6) strongly disagreed that community pharmacists are able to safely dispense and provide advice for animal prescriptions. Thirty-eight percent (n = 8) of the veterinary surgeons disagreed, and 33% (n = 7) strongly disagreed that pharmacists are able to give advice for certain chronic conditions, seen in humans, that are also seen in animals. Figure 3.5 and Figure 3.6 show the perception of veterinary surgeons in this regard.

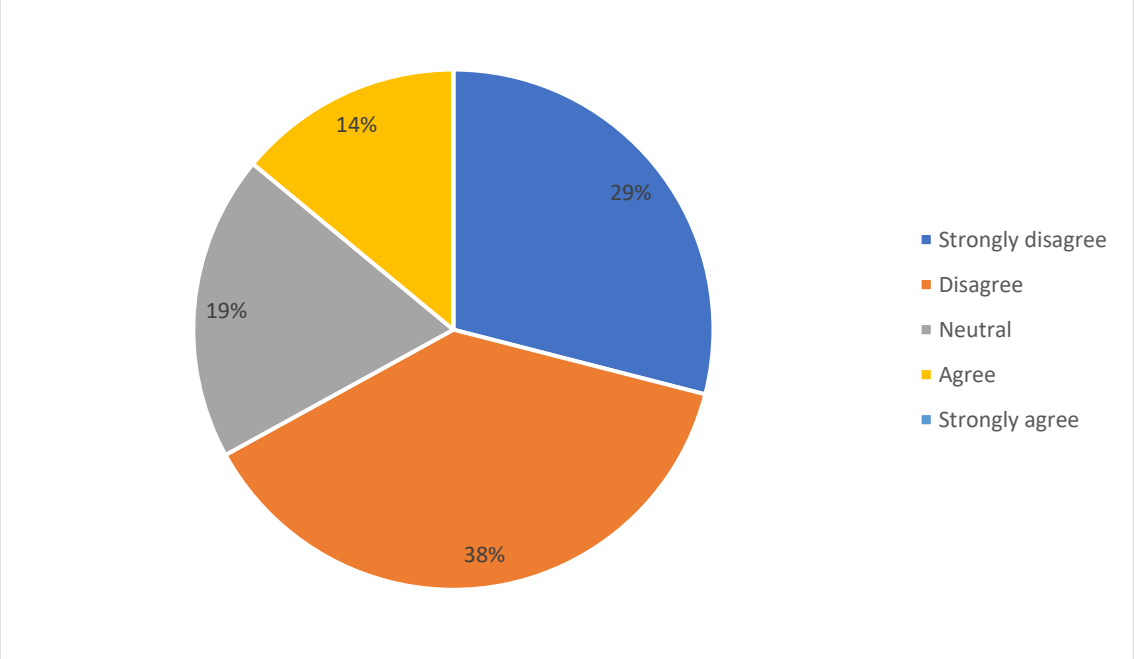

Figure 3.5: Perception of the veterinary surgeons on whether pharmacists are able to safely dispense medicines for use in animals (N=21)

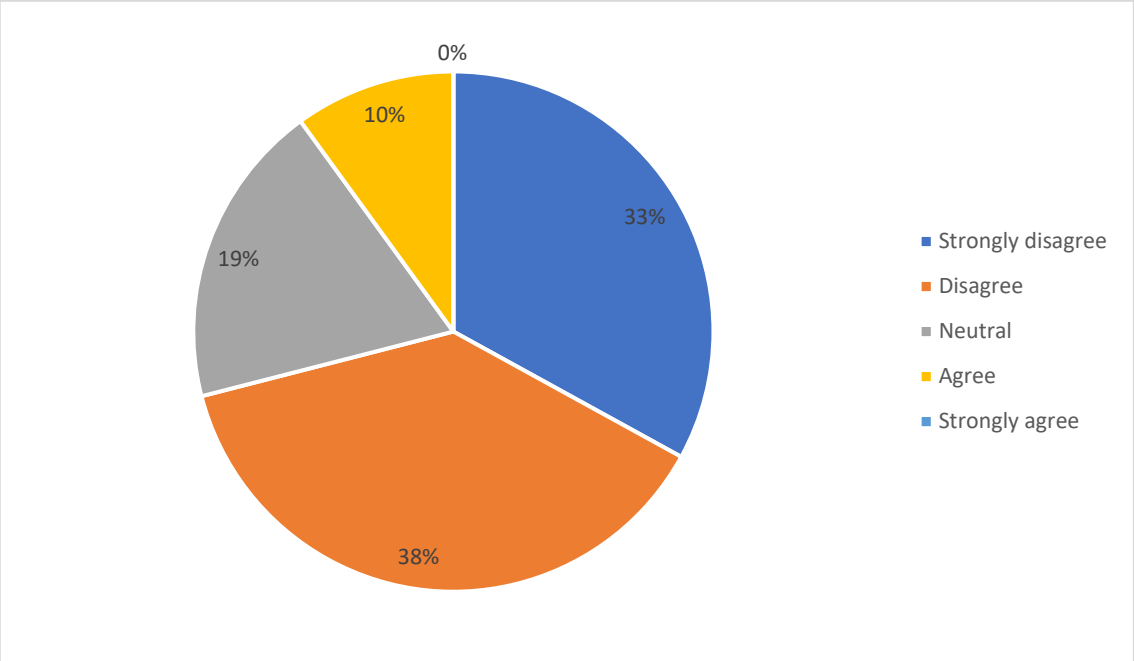

Figure 3.6: Perception of the veterinary surgeons on whether pharmacists are able to provide advice for chronic conditions see in animals that are also seen in humans (N=21)

Thirty-eight percent (n = 8) of veterinary surgeons disagreed and 14% (n = 3) strongly disagreed that community pharmacists have the knowledge and expertise to compound medications for pets. Thirty-three percent (n = 7) neither agreed nor disagreed with this statement. Ten percent (n = 2) agreed that pharmacists have knowledge and expertise while 5% (n = 1) strongly agreed.

Community pharmacists should be given training to understand the differences in animal physiology and provide appropriate drug information to support pet owners and serve as inter-professional collaborators with veterinary surgeons. This statement was agreed upon by 52% (n = 11) of veterinary surgeons. Twenty-four percent (n = 5) strongly agreed. Figure 3.7 shows the responses given by veterinary surgeons.

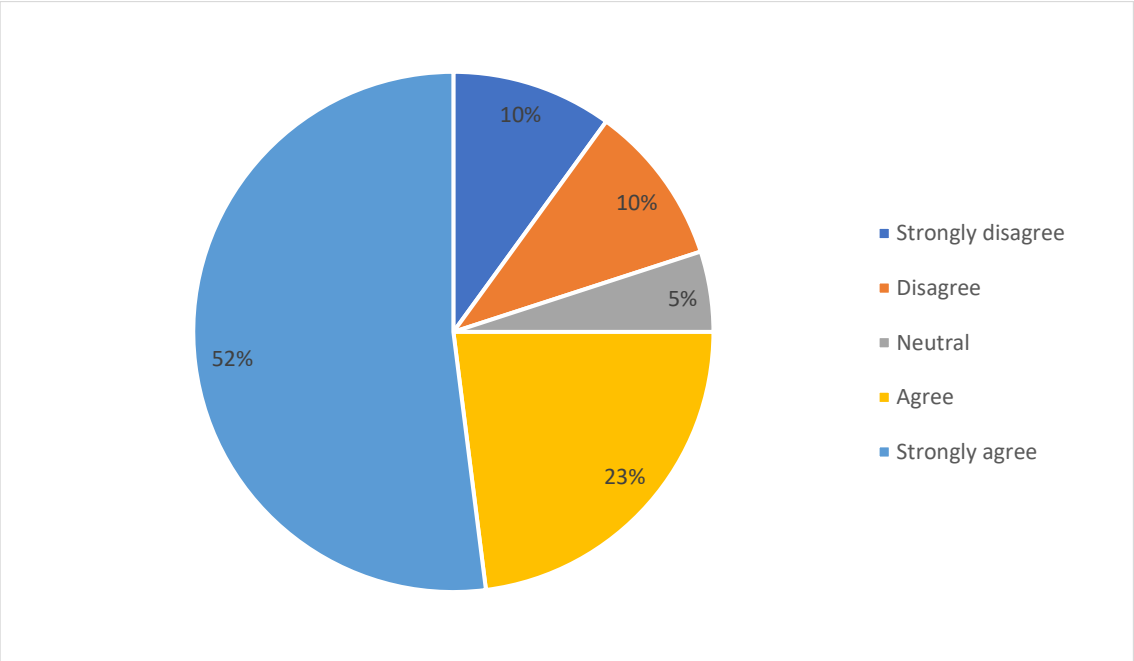

Figure 3.7: Perception of the veterinary surgeons on whether pharmacists should be given training in veterinary pharmaceutical sciences (N=21)

Veterinary surgeons were asked to indicate how pharmacists can increase their knowledge in veterinary therapeutics by selecting from various options. Eighty-one percent (n = 17) agreed that training programmes should be designed in the form of short courses, while 67% (n = 14) indicated that study modules and/or units should be included in established curricula. Fifty-two percent (n = 11) indicated that students should have placements in veterinary clinics to increase their knowledge. Figure 3.8 shows the responses from the veterinary surgeons in this regard. Others include obtaining a veterinary surgeon's degree and a comment regarding the need for the pharmacist to simply follow the veterinary surgeon's instructions.

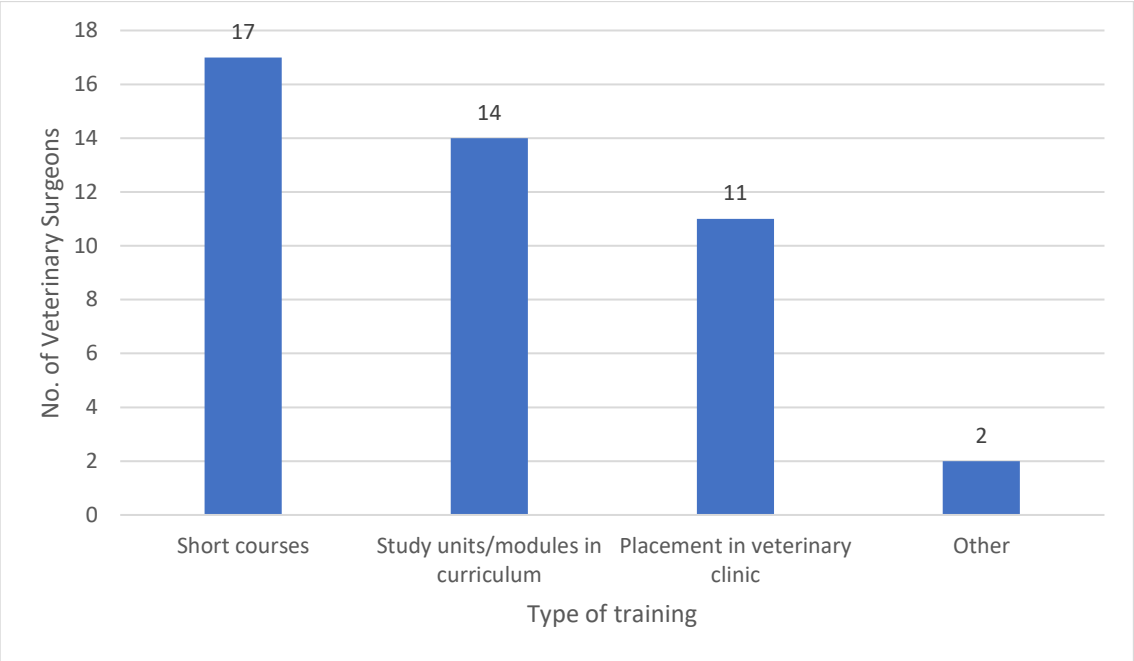

Figure 3. 8: The veterinary surgeons' perception on how pharmacists can increase their knowledge in veterinary pharmaceutical sciences (N = 21)

Forty-eight percent (n = 10) strongly agreed that there is a need for pharmacists and veterinary surgeons to collaborate to provide the best care for animals. Thirty-three percent (n = 7) of the veterinary surgeons also agreed with this statement. Fourteen percent (n = 3) neither agreed nor disagreed while 5% (n = 1) strongly disagreed. When analysing age of the veterinary surgeons and whether there is the need for interprofessional collaboration to provide the best care for animal patients, a statistically significant difference was observed (p = 0.009), indicating that the younger age groups are more in favour of interprofessional collaboration.

Pharmacists are able to help veterinary surgeons navigate the wealth of information on drug products to assist them in making appropriate choices. Thirty-three percent (n = 7) agreed with this statement. Another 33% (n = 7) neither agreed nor disagreed. Fourteen percent (n = 3) strongly agreed with this statement, while another 14% (n = 3) disagreed.

Five percent (n = 1) of veterinary surgeons strongly disagreed that pharmacists are able to help veterinary surgeons.

Thirty-eight percent (n = 8) of veterinary surgeons agreed that the pharmacist is underutilised and not involved in veterinary therapeutics. Another 38% (n = 8) neither agreed nor disagreed with this statement. Fourteen percent (n = 3) strongly agreed while 5% (n = 1) disagreed and another 5% (n = 1) strongly disagreed that pharmacists are underutilised.

Fifty-two percent (n = 11) of veterinary surgeons agreed that they would consider collaborating with a community pharmacist to increase the access to medicine that is safe and effective. Nineteen percent (n = 4) strongly agreed. Fourteen percent (n = 3) neither agreed nor disagreed, 10% (n = 2) disagreed and 5% (n = 1) strongly disagreed.

Fifty-two percent (n = 11) veterinary surgeons agreed that they would consider collaborating with community pharmacists to provide compounded medication to patients. Twenty-four percent (n = 5) strongly agreed. Fourteen percent (n = 3) had a neutral position while 5% (n = 1) disagreed and another 5% (n = 1) strongly disagreed.

Veterinary surgeons were asked whether they are concerned that collaborating with community pharmacists will be detrimental to their practice in different ways. Forty-eight percent (n = 10) disagreed that this collaboration would result in a loss of revenue for their practice. Twenty-eight percent (n = 6) neither agreed nor disagreed. Fourteen percent (n = 3) agreed while 5% (n = 1) disagreed and another 5% (n = 1) strongly disagreed. Forty-three percent (n = 9) of veterinary surgeons disagreed that collaborating

with a community pharmacist to provide compounded medicine to their patients would result in a communication barrier between the pet owners and themselves. Thirty-two percent (n = 7) were neutral and 10% (n = 2) strongly disagreed. Another 10% (n = 2) agreed and 5% (n = 1) strongly agreed.

Sixty-two percent (n = 13) of veterinary surgeons agreed, and 23% (n = 5) strongly agreed, that enhancing veterinary-pharmacy interprofessional education can benefit both professions. Ten percent (n = 2) neither agreed nor disagreed with this statement and 5% (n = 1) strongly disagreed.

Veterinary surgeons were asked to choose and/or suggest other services that could be offered by a community pharmacy. Seventy-six percent (n = 16) would like veterinary medicinal products to be handled in the same way as human medicinal products. Sixty-seven percent (n = 14) would like community pharmacies to stock veterinary medicinal products. Compounding for animals was suggested by 57% (n = 12) of the veterinary surgeons. Figure 3.9 shows the services suggested by veterinary surgeons.

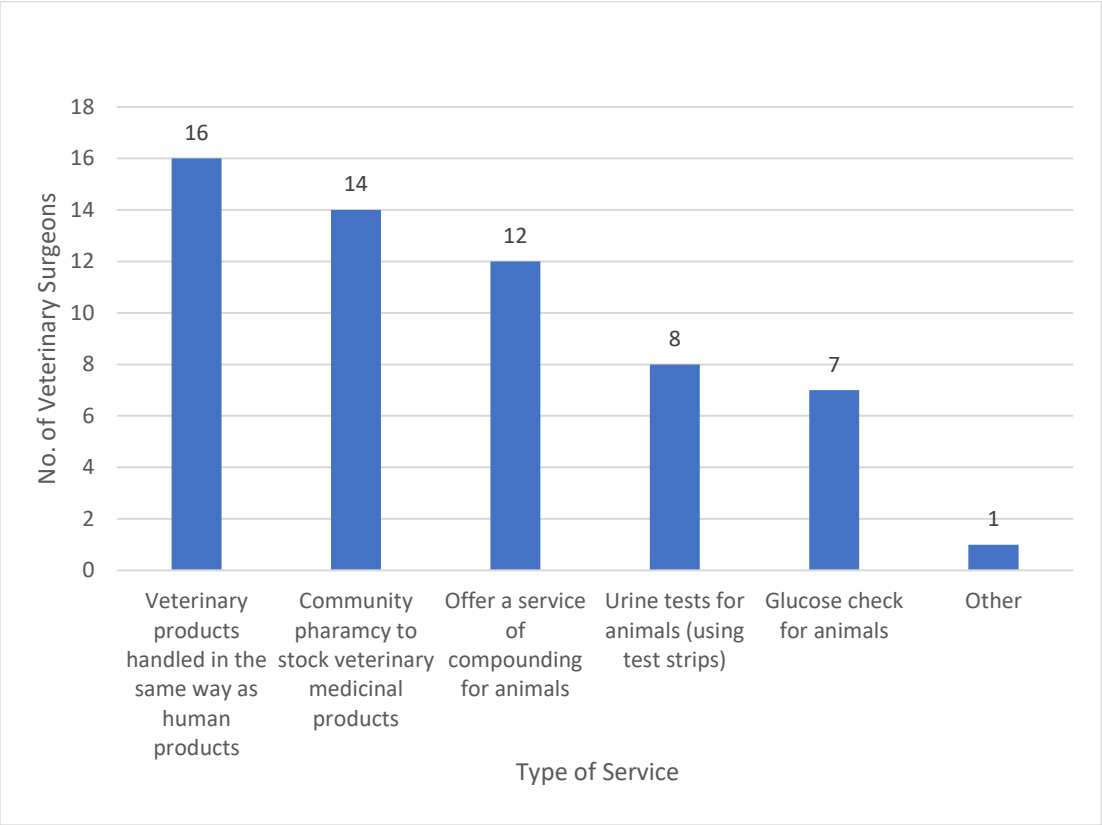

Figure 3.9: Other services that can be offered by a community pharmacy as suggested by veterinary surgeons (N = 21)

3.1.3. The perception of the role of the pharmacist, challenges and barriers regarding access to medicinal products and animal care

Ninety-one pharmacists compiled the questionnaire. Seventy-two percent (n = 66) of the respondents were female and 28% (n = 25) were male. Thirty-six percent (n = 32) of the pharmacists were aged between 18 and 29 years, 32% (n = 29) between 30 and 39 years, 21% (n = 19) between 40 and 49 years, 10% (n = 9) between 50 and 59 years and 1% (n = 1) between 60 and 69 years of age.

Pharmacists were asked to indicate their areas of practice within the last five years. Sixty-eight percent (n = 62) practised in a community pharmacy, 41% (n = 37) were involved in regulatory affairs and 14% (n = 13) practiced in a hospital setting. Others included

medical representation, marketing, policy, distribution and primary healthcare. Figure 3.10 shows the number of pharmacists per area of practice.

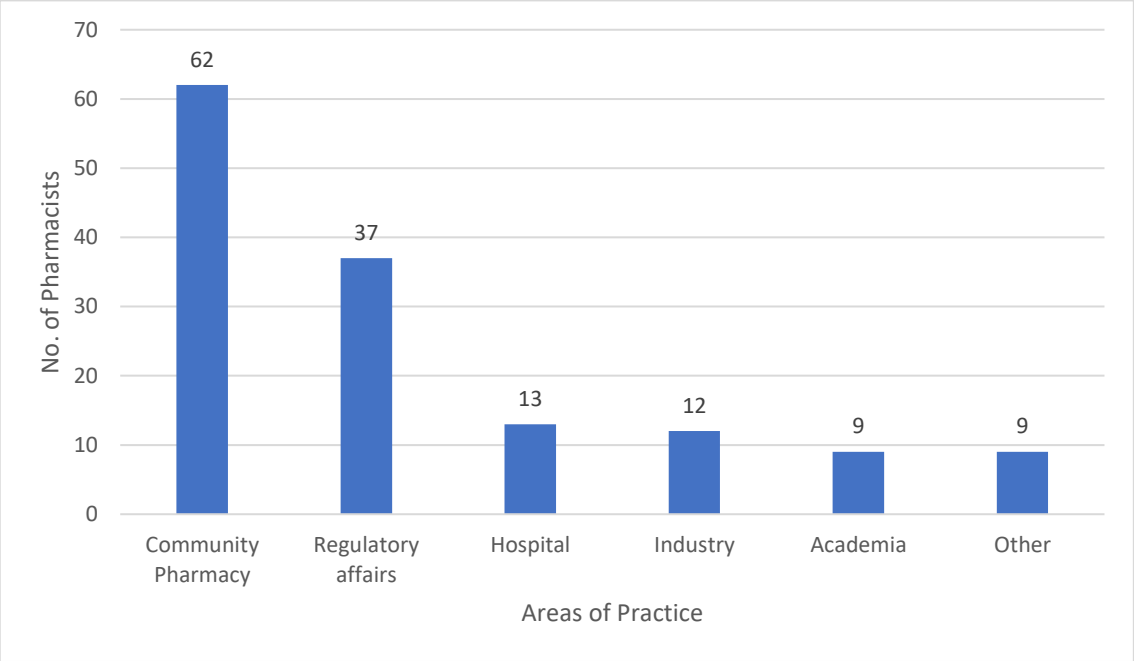

Figure 3.10: The distribution of the pharmacists within different sectors (N=91)

Five percent (n = 4) of pharmacists have been practicing within the community for less than 1 year. Forty-seven percent of the pharmacists (n = 39) have been practicing as a pharmacist within the community setting between 1 and 5 years. Eighteen percent (n = 15) between 6 and 10 years and 30% (n = 25) of the pharmacists have been practicing for more than 10 years. Table 3.1 shows the distribution of the location of practice of pharmacists. The most reported location of practice was that of the Northern Harbour district followed by the Southern Harbour district.

Table 3. 1: The distribution of the location of practice of pharmacists

District	Number of Pharmacists
Southern Harbour	22
Northern Harbour	26
South Eastern	12
Western	9
Northern	15
Gozo and Comino	1
Unspecified	18

Pharmacists were asked how often they dispensed medication for use in animals, against a prescription from a veterinary surgeon. Forty-six percent (n = 39) dispense medication on a monthly basis, 18% (n = 15) on a weekly basis and 18% (n = 15) on a yearly basis. Figure 3.11 shows the frequency of the pharmacist dispensing medicinal products for use in animals.

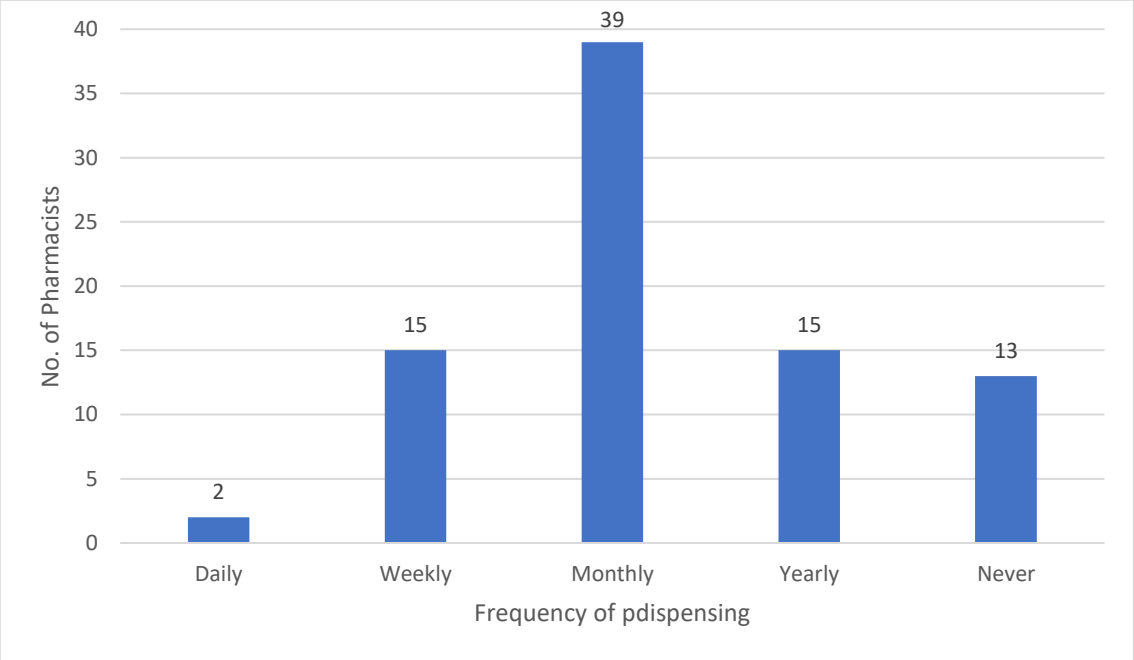

Figure 3.11: the frequency of the pharmacist dispensing medicinal products for use in animals (N = 91)

Ninety-five percent (n = 76) of pharmacists do not perform compounding for medicinal products against a veterinary surgeon's prescription. Out of those pharmacists who perform compounding 86% (n = 6) prepare individualised dosage forms, 43% (n = 3) prepare individualised medication or dose strength and 29% perform medication flavouring. Fourteen percent (n = 1) prepare combination medicines.

Two percent (n = 2) of the pharmacists indicated that pet owners asked them for advice on a daily basis, 20% (n = 17) on a weekly basis, 47% (n = 39) on a monthly basis and 18% (n = 15) were asked for advice on a yearly basis. Thirteen percent (n = 11) of pharmacists were never asked for advice about their pets. When analysing the locality of practice and how often pet owners asked the pharmacist for advice, a statistically significant difference was observed ($p = 0.006$).

Fifty-three percent (n = 44) of the pharmacists stated that they have had to look up information regarding animals, certain conditions animals suffer from, medication use in animals and administration to animals to be able to give advice to pet owners. Online searches were the most common resource used, as reported by 80% (n = 37) of the pharmacists, to find information. Fifteen percent (n = 7) referred to peer-reviewed journal articles. Four percent (n = 2) referred to the MSD Veterinary Manual and 1% (n = 1) used the BSAVA small animal formulary. Two percent (n = 1) used resources from the Harper Adams University Library and another 2% (n = 1) asked a veterinary surgeon.

Pharmacists were asked whether or not they were aware of the challenges pet owners faced when administering medication to their pets. Sixty percent (n = 54) of pharmacists are aware of the challenges and 31% percent (n = 28) were not aware of these challenges. According to pharmacists the biggest challenge pet owners face when giving medication to their pets is that the pet would not eat or swallow the medication as reported by 38% (n = 35) of pharmacists. This is followed by the medication dosing/administration being difficult or messy and being injured by the pet whilst trying to give the medication as indicated by 26% (n = 24) and 24% (n = 22) of pharmacists respectively . Figure 3.12 shows the challenges as reported by pharmacists.

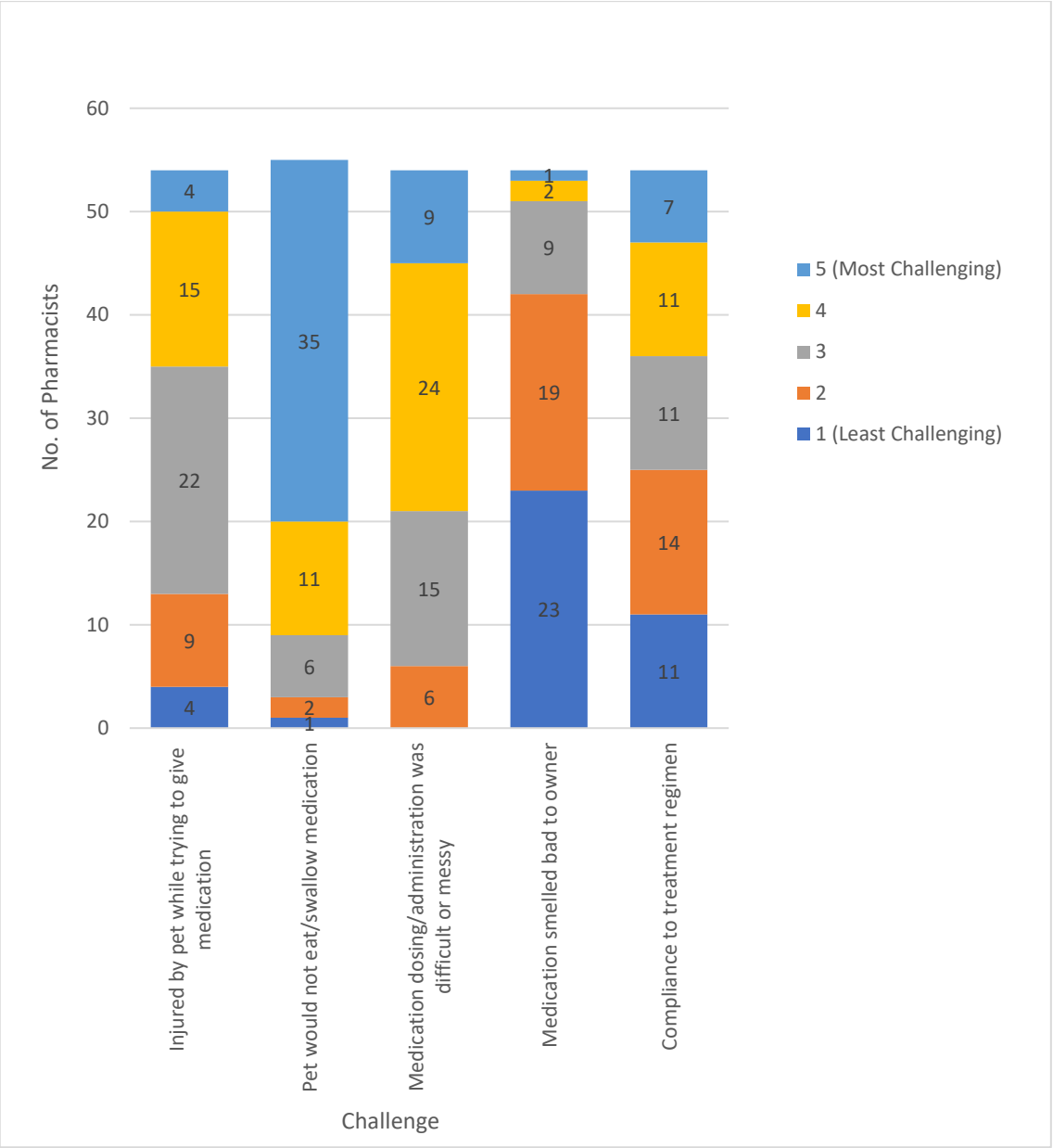

Figure 3.12: The challenges pet owners face when administering medication to animals, as reported by pharmacists (N=54)

Sixty-four percent (n = 58) of pharmacists were not aware of the challenges veterinary surgeons face when deciding on treatment options for their patients. Twenty-four percent (n = 21) were aware. When analysing the locality of practice and whether pharmacists were aware of the challenges veterinary surgeons face, a statistically significant difference was observed (p = 0.022) indicating that location affects the pharmacist's

awareness of challenges. According to pharmacists, the biggest challenges faced by veterinary surgeons is that the medicinal product required is not available in the community, as reported by 48% (n =10) of pharmacists. This was followed by the fact that there is no access to medicinal products that are only available from hospital (43%, n=9). Thirty-eight percent (n=8) of pharmacists reported that a challenge is that the dosage form available is not appropriate for animal administration. Figure 3.13 shows the degree of challenge as reported by pharmacists.

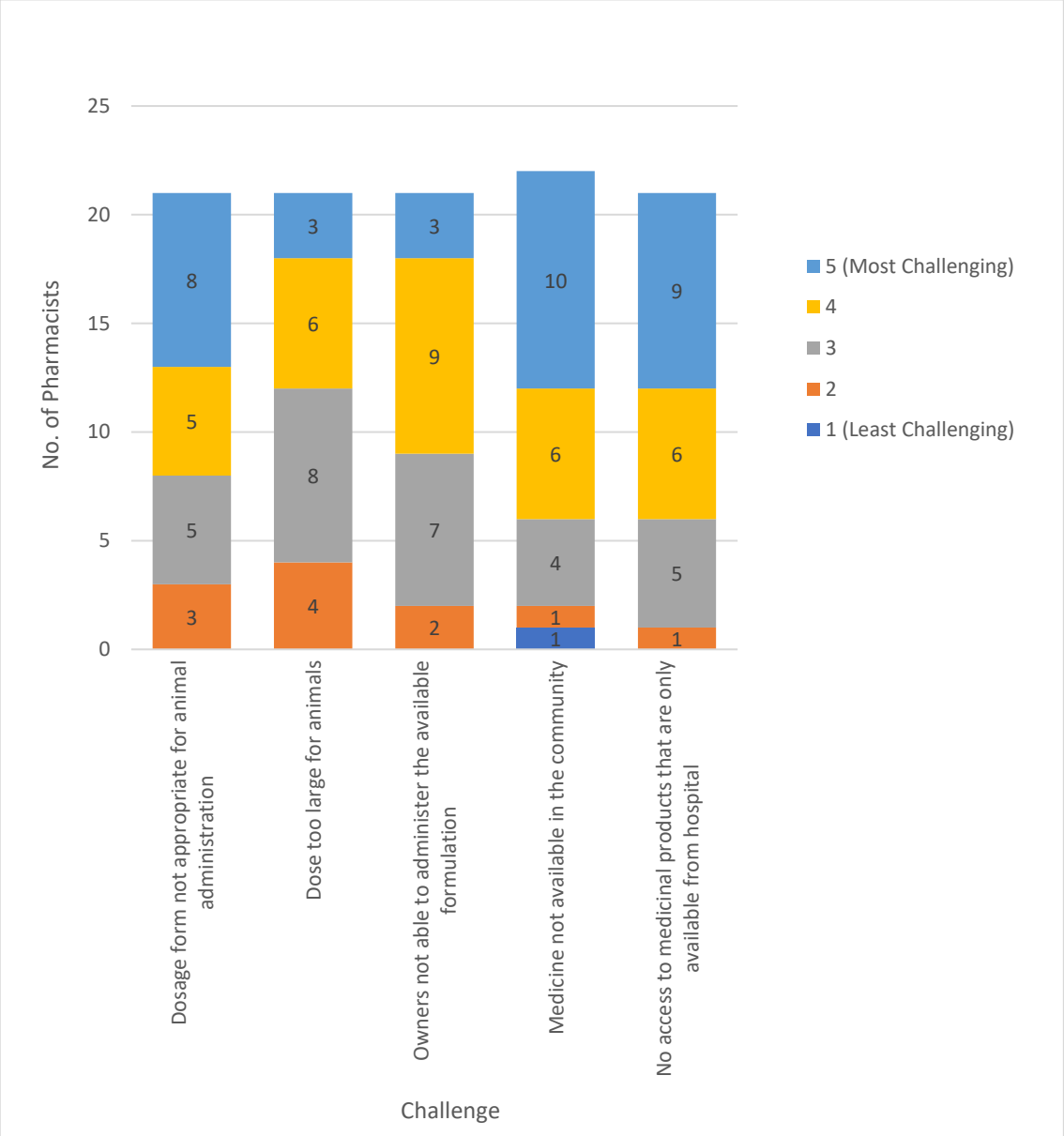

Figure 3.13: the challenges pet owners face when administering medication to animals, as reported by pharmacists (N=21)

According to 69% (n = 59) of the pharmacists, the main motivations behind veterinary surgeons prescribing human medicines for use in animals is that the veterinary medicinal product required is not available. Fifty-five percent (n = 47) indicated that it is because veterinary equivalents do not exist and 36% (n = 31) are of the opinion that there is a problem for pet owners to access a veterinary clinic or veterinary pharmacy. Four percent (n = 3) indicated that human medicine for use in animals is not prescribed and 14% (n = 12) did not know which are the main motivations behind prescribing human medicinal products for use in animals.

Forty-eight percent (n = 44) of the pharmacists disagreed that community pharmacists possess competence in caring for veterinary patients and 23% (n = 21) strongly disagreed. Twenty-three percent (n = 21) neither agreed nor disagreed. Three percent (n = 3) agreed with this statement and 2% (n = 2) strongly agreed.

Forty-six percent (n = 42) of pharmacists disagreed that community pharmacists are prepared to safely dispense and provide advice for animal prescriptions and 23% (n = 21) strongly disagreed. Figure 3.14 shows the level of agreement with this statement.

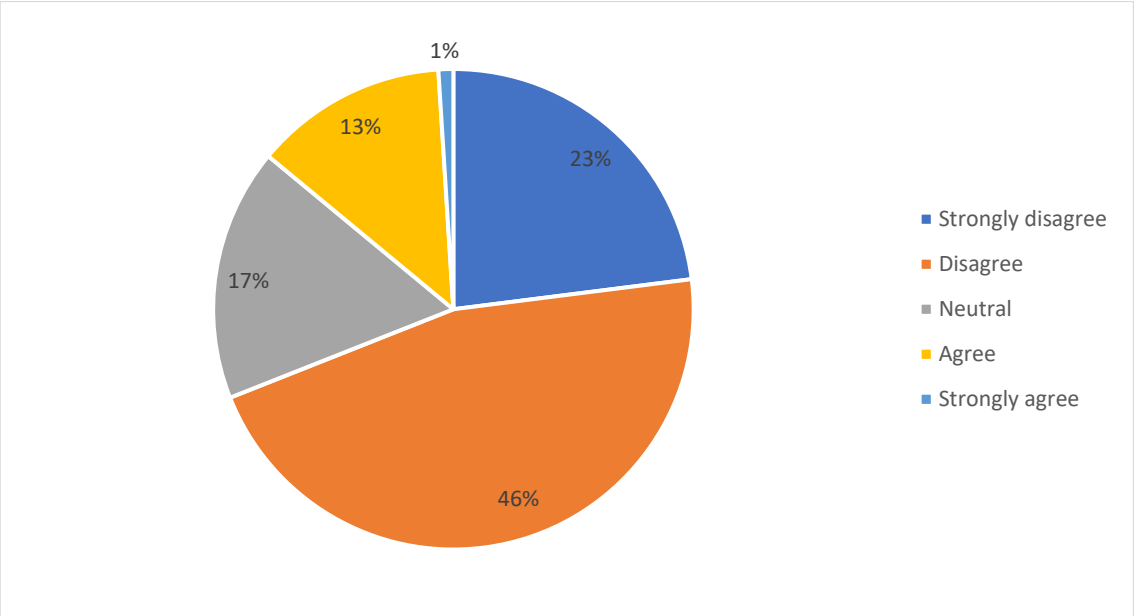

Figure 3.14: The perception of the pharmacist on whether they are able to safely medicines for use in animals (N=91)

Forty-one percent (n = 37) of pharmacists disagreed that pharmacists are able to give advice for certain chronic conditions seen in humans that are also seen in animals. Twenty-seven percent (n = 25) gave a neutral answer and 18% (n = 16) strongly disagreed with this statement. Figure 3.15 shows the level of agreement with this statement.

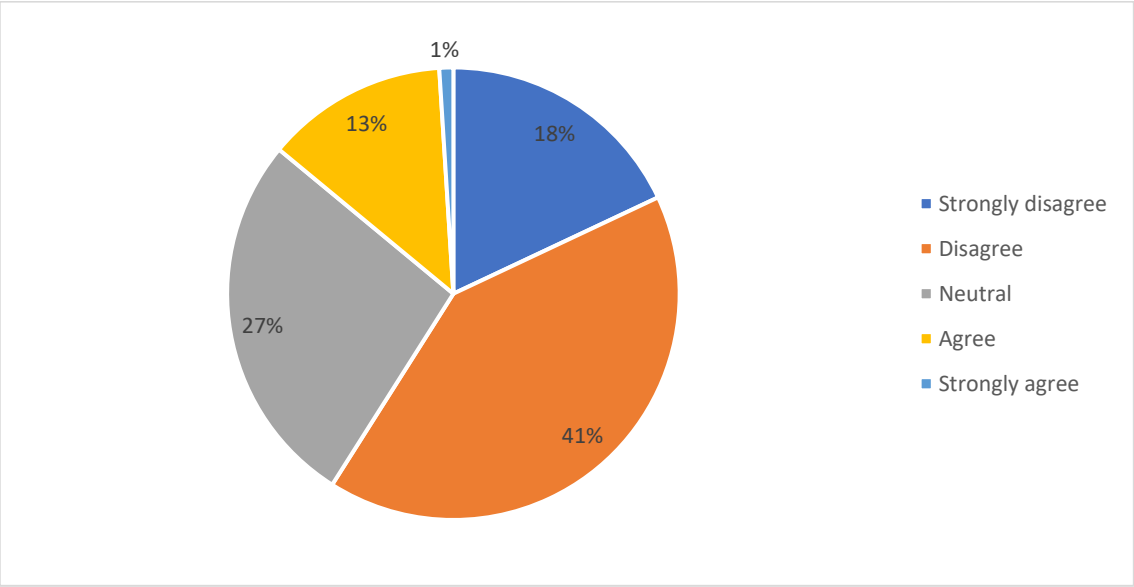

Figure 3.15: The perception on the ability of pharmacists to provide advice for chronic conditions seen in animals (N=91)

Thirty-one percent (n = 28) disagreed that pharmacists have the knowledge and expertise to compound medication for pets, 24% (n = 22) were neutral and 22% (n = 20) strongly disagreed. Twenty percent (n = 18) agreed and 3% (n = 3) strongly agreed with this statement.

Forty-seven percent (n = 43) of pharmacists agreed and 31% (n = 28) strongly agreed, that community pharmacists should be given training to understand the differences in animal physiology and provide appropriate drug information to support pet owners and serve as interprofessional collaborators with veterinary surgeons. Thirteen percent (n = 12) neither agreed nor disagreed. Eight percent (n = 7) disagreed and 1% (n = 1) strongly disagreed with this statement.

Pharmacists were asked to indicate how pharmacists can increase their knowledge in veterinary therapeutics. Eighty-one percent (n = 70) indicated that training programmes for pharmacists should be designed in the form of short courses. Seventy-seven percent (n = 66) would like study units and/or modules to be included in curricula. Students having placements in veterinary pharmacy was selected by 62% (n = 53) of respondents. Others (5%) included having post-graduate (master courses) degrees in veterinary pharmacies and continuing education. This is represented in Figure 3.16.

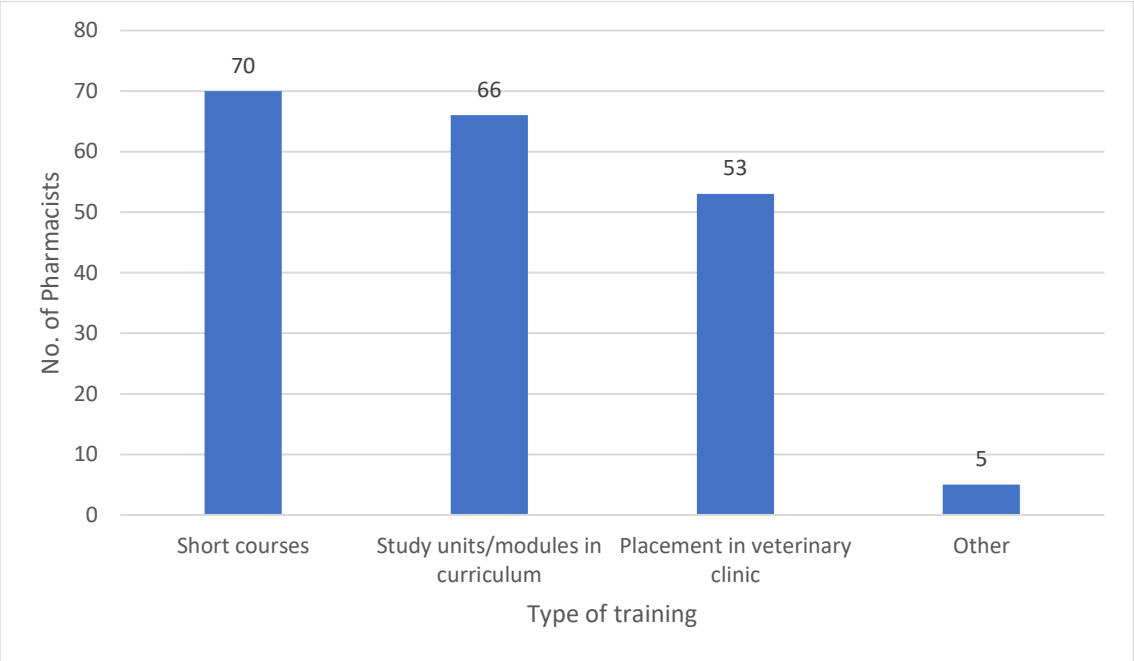

Figure 3.16: The suggested methods of how pharmacists can increase their knowledge in veterinary pharmaceutical sciences (N=91)

There is the need for pharmacists and veterinary surgeons to collaborate to provide the best care for animal patients. Fifty-six percent (n = 51) of the pharmacists agree, and 30% (n = 27) strongly agreed with this statement. Seven percent (n = 7) neither agreed nor disagreed, 6% (n = 5) disagreed and 1% (n = 1) strongly disagreed.

Fifty-one percent (n = 46) of pharmacists agree that pharmacists are able to help veterinary surgeons navigate the wealth of information on drug products to assist them in making appropriate drug choices. Twenty-five percent (n = 23) are neutral, 15% (n = 13) strongly agree, 5% (n = 5) disagree and 4% (n = 4) strongly disagree with this statement. When analysing length of years of practice and the pharmacist's ability to help veterinary surgeons navigate the wealth of information available, a statistically significant difference was observed (p=0.020). A statistically significant difference (p = 0.022) was observed when analysing locality of practice and pharmacist's ability to help veterinary surgeons.

Sixty-two percent (n = 56) of the pharmacists agree that pharmacists are underutilised and not involved in veterinary therapeutics. Twenty-two percent (n = 20) agree with this statement. Thirteen percent (n = 12) neither agree nor disagree while 3% (n = 3) disagreed.

Collaboration between community pharmacists and veterinary surgeons increases the access to medicine that is safe and effective. Sixty-six percent (n = 60) of the pharmacists agreed, and 23% (n = 21) strongly agreed with this statement. Eight percent (n = 7) were neutral, 2% (n = 2) strongly disagreed and 1% (n = 1) disagreed.

Fifty-nine percent (n = 54) of pharmacists agreed that pharmacists and veterinary surgeons should collaborate to provide compounded medication to animal patients. Twenty percent (n = 18) were neutral, 18% (n = 16) strongly agreed, and 3% (n = 3) disagreed.

Community pharmacists involved in veterinary therapeutics may be perceived as direct competitors by veterinary surgeons. Forty-six percent (n = 42) disagreed with this statement and 7% (n = 6) strongly disagreed. Thirty percent (n = 27) neither agreed nor disagreed, 14% (n = 13) agreed and 3% (n = 3) strongly agreed. Sixty-three percent (n = 57) of pharmacists agreed and 30% (n = 27) strongly agreed that enhancing veterinary-pharmacy interprofessional education can benefit both professions.

Pharmacists were asked to choose and/or suggest other veterianry-related services that could be offered by a community pharmacy. Seventy-six percent (n = 64) would like community pharmacies to stock veterinary medicinal products. Sixty-nine percent (n =

58) would like veterinary medicinal products to be handled in the same way as human medicinal products. Compounding for animals was suggested by 55% (n = 46) of the pharmacists. Pharmacists agreed that a community pharmacy could offer testing such as glucose testing and perform urine tests. Figure 3.17 shows the services suggested by pharmacists. Others (4%) included that there should be a clampdown on illegal veterinary medicine and to avoid using a community pharmacy as a veterinary pharmacy.

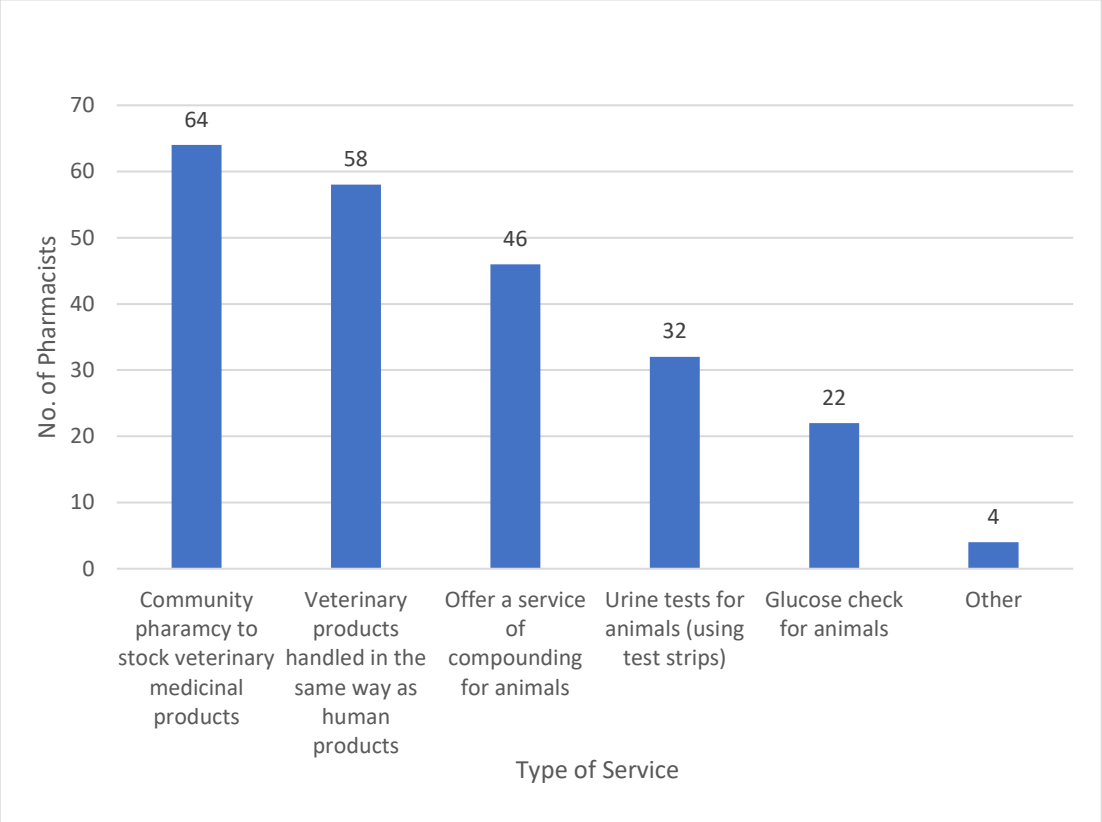

Figure 3.17: The services pharmacists would like to be offered by a community pharmacy (N=91)

3.1.4. The Pet Owner's Perception of the Role of the Pharmacist, Challenges and Barriers Regarding Access to Medicinal Products and Animal Care

Two hundred and thirty-two pet owners compiled the questionnaire. Eighty-four percent (n = 195) of the respondents were female and 16% (n = 37) were male. Twenty-seven

percent (n = 62) of the respondents were aged between 18 and 29 years, 31% (n = 73) between 30 and 39 years, 17% (n = 39) between 40 and 49 years and 16% (n = 38) between 50 and 59 years. Eight percent (n = 18) were aged between 60 and 69 years and 1% (n = 2) over 70 years of age.

The localities of residence of the respondents were assigned to the Local Administrative Units (LAU) as specified by the National Statistics Office (NSO). Thirty-one percent (n = 72) reside in the Northern district and 25% (n = 59) reside in the Northern Harbour district. Two percent (n = 5) did not specify their location of residence.

Table 3.2: The localities of residence of the pet owners that compiled the POP-Q (N=232)

District	Number of pet owners	Percentage (%) of total respondents
Northern	72	31
Northern Harbour	59	25
Southern Harbour	39	17
Western	29	13
South Eastern Harbour	25	11
Gozo and Comino	3	1
Unspecified	5	2

Fifty-seven percent (n = 135) have a tertiary level of education. Twenty-five percent (n = 59) have a post-secondary level of education and 15% possess a secondary level of education. A primary level of education, work and vocational school were each selected by 1% (n =1) of respondents.

The respondents were asked how many pets they currently have. Thirty-two percent (n = 74) have 1 pet and 23% (n = 53) have 2 pets. Sixteen percent (n = 3) stated that they currently have 3 pets and 10% (n = 19) stated that they have 4 pets. Twenty-one percent (n = 49) stated that they currently have more than 5 pets.

Pet owners were asked to indicate what type of pets they have. The most common type of pets were dogs and cats as indicated by 61% (n = 142) and 53% (n = 123) pet owners respectively. One percent (n = 2) of pet owners included mammals, and domestic animals as 'Other'. Figure 3.18 shows the different types of pets as indicated by pet owners.

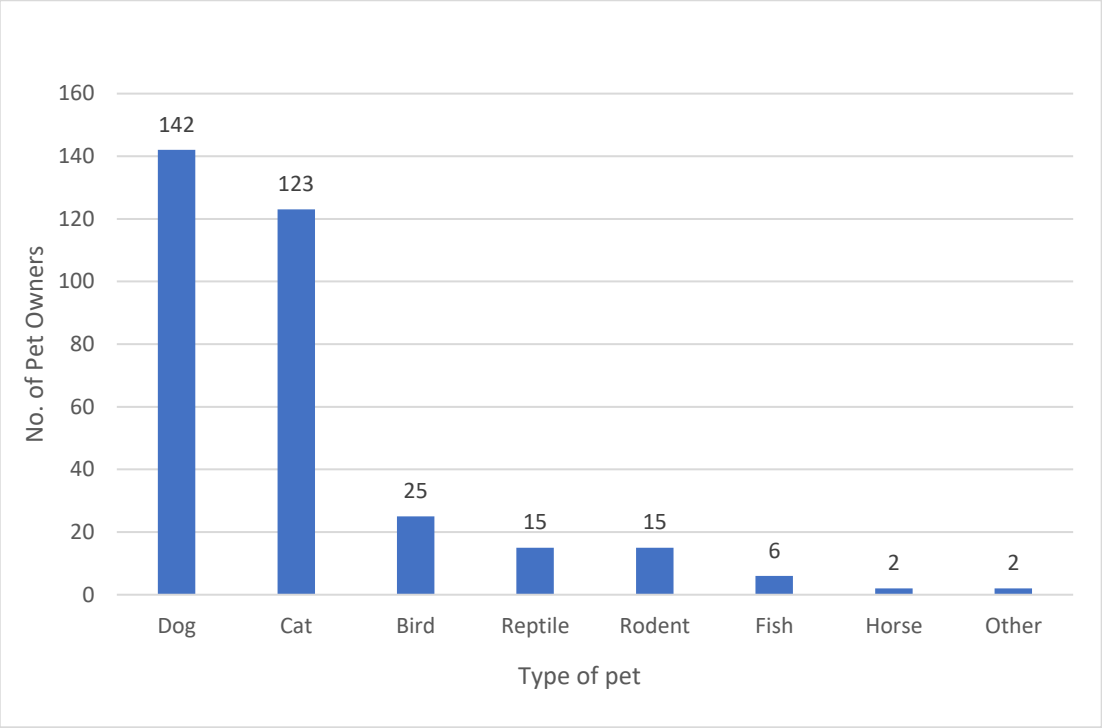

Figure 3.18: The types of pets as indicated by pet owners (N=232)

Sixty-one percent (n = 141) have pets that are between 1 and 5 years of age. Fifty-six percent (n = 131) have pets that are between 6 and 10 years of age. Thirty-one percent (n = 71) have pets that are older than 10 years of age and 16% (n = 7) have pets younger than one year. Fifty-seven percent (n = 132) have pets who do not have any health problems while 40% (n = 92) have pets with one or several health problems. Three percent (n = 8) did not know if their pet had any health issues.

Those pet owners who had pets with health problems were asked to list the problems their pet had at the time of completing the questionnaire. The most common condition seen in pets was bone disorders, including arthritis and hip dysplasia (26%, n=24) followed by cardiac disorders (15%, n=14) and renal disorders (13%, n=12). Nine percent (n=8) indicated that their pet suffered from 'Other' disorders including leishmaniasis, ringworm and hernias. Figure 3.19 shows the number of pets affected by different conditions.

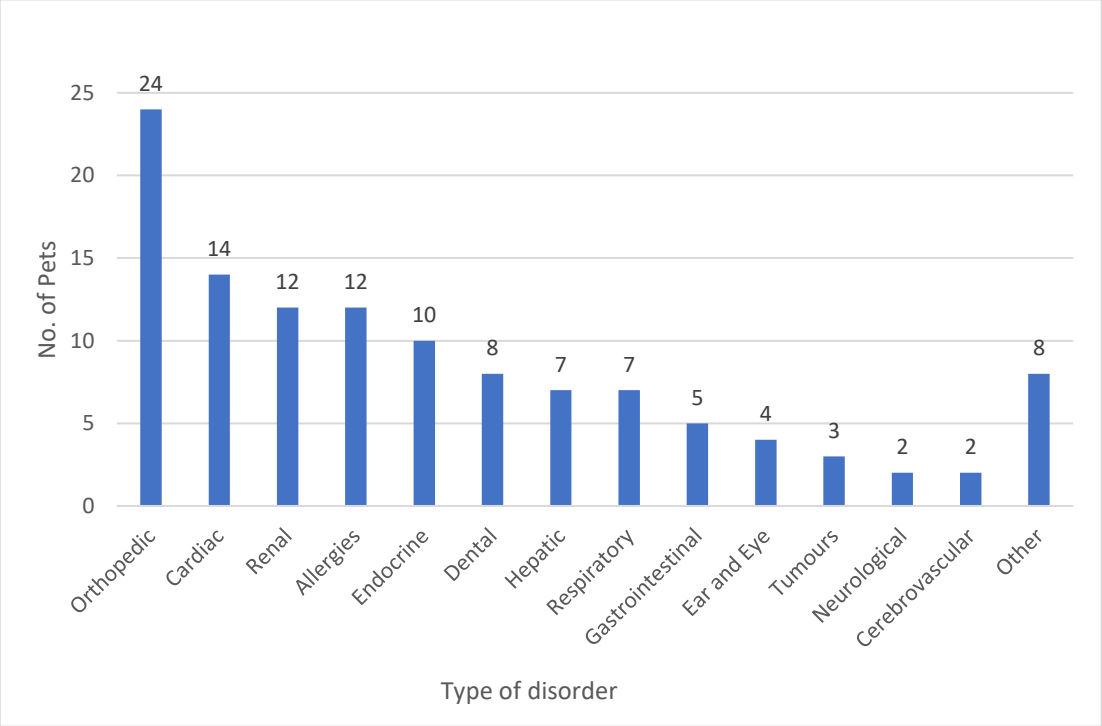

Figure 3.19: The number of pets affected by different conditions as indicated by pet owners (N=93)

Seventy-two percent (n = 167) of pets had been prescribed medications in the six months prior to the completion of the questionnaire, while 64% (n = 64) had not. One percent (n = 1) of pet owners were not sure whether their pet had been prescribed any medications. Seventy-three percent (n = 170) of pet owners purchased their medicines from a veterinary clinic. Thirty-two percent (n = 73) purchased medicines for their pets from a veterinary pharmacy, 18% (n = 42) purchased medicines from a community pharmacy.

Three percent (n = 8) purchased medication for their pet online, and 1% (n = 1) of pet owners purchased medication either from the veterinary surgeon during a house call, delivered by the veterinary surgeon, from a pet shop or from a sanctuary rescue centre.

Fifty-one percent (n = 118) of pet owners stated that they have been prescribed a medicine that needed to be purchased from a community pharmacy while 44% (n = 102) had not. Five percent (n = 12) were not sure. Seventy-three percent (n = 170) of pet owners indicated that they had never been prescribed a medicine that needed to be compounded, 10% (n = 22) had, and 17% (n = 40) were not sure. When analysing the locality of residence and if pets were ever prescribed medication that needed to be compounded, a statistical significance was observed (p = 0.014).

Pet owners were asked to indicate which dosage form(s) are their pet's medicines. The most common dosage form used by pets is the tablet (74%, n=172). This was followed by injectables (27%, n=63) and cream/ointment (25%, n=57). Two percent (n = 5) of pet owners indicated that medicated food was given to their pets. Others dosage forms included drops to be used on the skin, nebuliser, paste, inhaler and powder, as indicated by 3% (n = 6) of pet owners. Figure 3.20 shows the use of different dosage forms as indicated by pet owners.

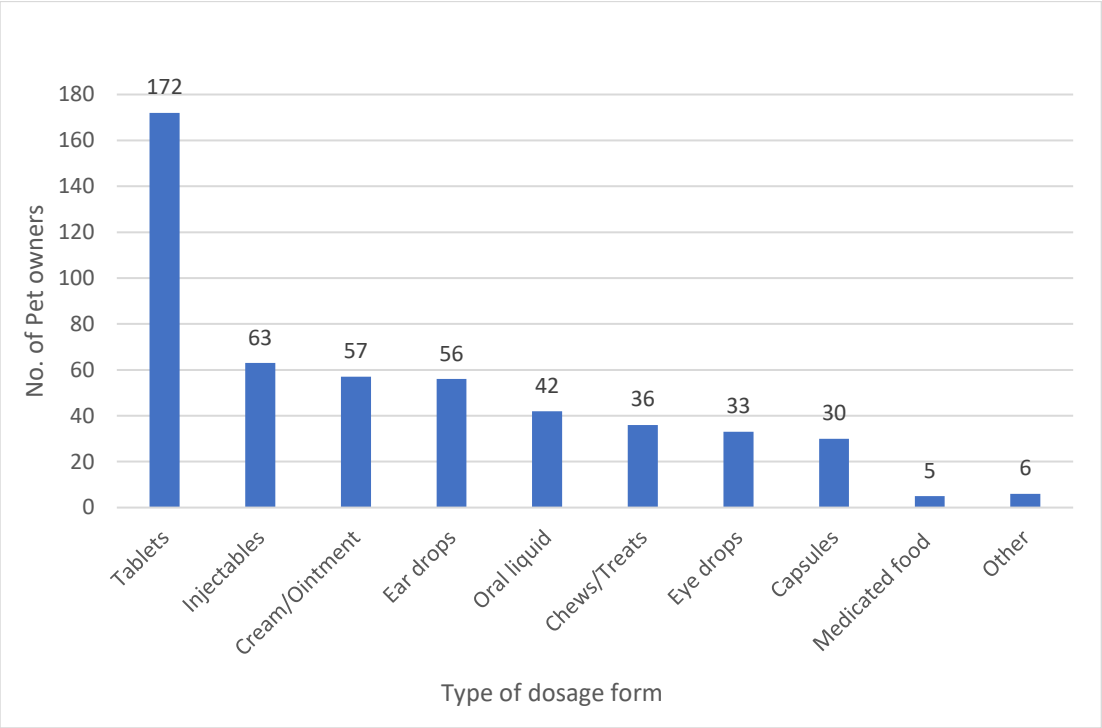

Figure 3.20: The different dosage forms of the medication administered to pets as indicated by the pet owners (N=232)

According to 29% (n = 68) of pet owners, it was difficult to administer medication to their pets. Twenty-six percent (n = 60) were neutral and 18% (n = 41) found it easy to administer medication. Seventeen percent (n = 40) found it extremely difficult to administer medication to their pets, while 10% (n = 23) found it extremely easy.

Pet owners were asked to identify what are their biggest challenges when administering medication to their pets. The most common challenges pet owners face (68%, n=158) is that their pet would not eat/swallow the medicine. This was followed by the pet becoming very stressed when trying to administer medication (44%, n=101). Figure 3.21 shows the various problems pet owners face when trying to administer medicine. Four percent (n=9) pointed out issues with giving the right dose when you have to cut the tablet in very small

pieces and finding the medicine even when hidden in food and certain medicines' smell is too strong for some pets.

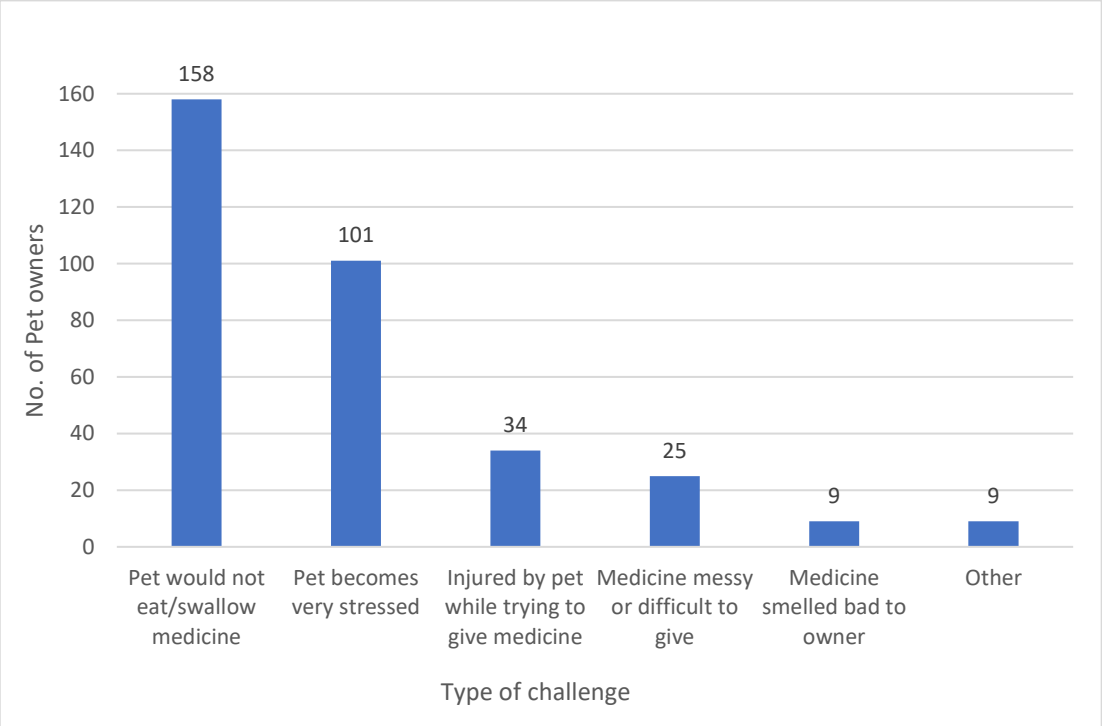

Figure 3.21: Challenges pet owners face when administering medication to animals as indicated by pet owners (N=232)

Sixty-one percent (n = 142) of pet owners never go to a community pharmacy and ask for advice about their pet and 19% (n = 44) rarely do so. Fourteen percent (n = 31) sometimes ask the community pharmacist for advice about their pet. Four percent (n = 10) do so frequently and 2% (n = 5) always go to a community pharmacy and consult the pharmacist. When analysing the locality of residence and how frequently pet owners went to a community pharmacy to ask for advice about their pet, a statistical significance was observed ($p = <0.001$). A statistically significant difference ($p = 0.007$) was also observed when analysing age and how frequently pet owners went to a community pharmacy for advice, indicating that younger generations are more inclined to ask the community pharmacist for advice.

Pet owners were asked whether community pharmacists are skilled in caring for companion animals. Forty-four percent (n = 103) neither agreed nor disagreed with this statement. Twenty-nine percent (n = 66) disagreed and 13% (n = 31) strongly disagreed that pharmacists are skilled; Twelve percent (n = 27) agree and 2% (n = 5) strongly agreed.

Thirty-six percent (n = 83) disagreed that community pharmacists have the knowledge to give advice regarding the administration, mode of action and side effects regarding human medicine use in animals. Thirty-three percent (n = 77) neither agreed nor disagreed with this statement. Sixteen percent (n = 38) agreed and 14% (n = 32) strongly disagreed. One percent (n = 2) strongly agreed that community pharmacists have the knowledge to give advice. When analysing the locality of residence and whether pet owners think the community pharmacist has the knowledge to give advice, a statistical significance was observed (p = 0.011) indicating that pet owners residing in the Northern District think that the community pharmacists have the knowledge to give advice regarding human medicine use in animals more than pet owners residing in the South Eastern District.

When asked whether community pharmacists have the knowledge and skills to compound medications for their pets, 44% (n = 102) of respondents neither agreed nor disagreed. Twenty-five percent (n = 58) disagreed and 18% (n = 42) agreed. Eleven percent (n = 25) strongly disagreed while 2% (n = 5) strongly agreed.

Thirty-six percent (n = 84) disagreed that community pharmacists can give advice on the chronic medical conditions that affect their pets. Thirty percent (n = 69) were neutral,

17% (n =39) strongly disagreed and 16% (n = 38) agreed. One percent (n = 2) strongly agreed that community pharmacists can give advice.

Fifty-five percent (n = 129) of pet owners strongly agreed that they prefer to ask the veterinary surgeon for advice regarding their pets' medication, medicinal products and chronic conditions that are also seen in humans, rather than a community pharmacist. Figure 3.22 shows to what extent respondents agreed or disagreed in this regard. When analysing the age and whether pet owners prefer to ask the veterinary surgeon for advice rather than the pharmacist, a statistical significance was observed (p = 0.039).

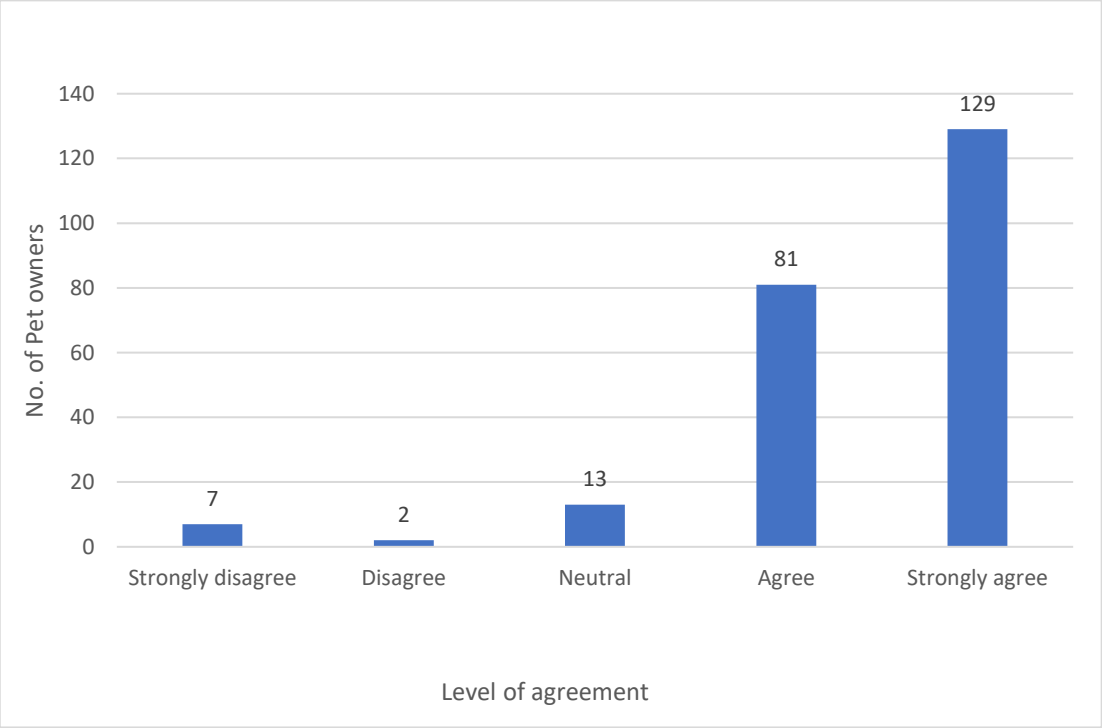

Figure 3.22: The pet owners' preference to ask the veterinary surgeon for advice rather than the pharmacist (N=232)

Forty-five percent (n = 104) neither agree nor disagree when asked whether they would benefit from having medicine compounded by a community pharmacist. Twenty-eight percent (n = 65) agree, 14% (n = 33) disagree, 9% (n = 20) strongly agree while 4% (n =

10) strongly disagree. When analysing the level of education and whether pet owners think that their pet may benefit from having medicines compounded by a community pharmacist, a statistical significance was observed ($p = 0.035$). A statistical significance was also observed ($p = 0.01$) between the locality of residence and the benefit of having medication compounded by a community pharmacist.

Pet owners were asked whether they would be willing to go out of their way to collect compounded medicine for their pet. Forty-four percent ($n = 101$) agreed that they would be willing to go out of their way and 33% ($n = 78$) strongly agreed. Seventeen percent ($n = 40$) were neutral, 5% ($n = 12$) disagreed and 4% ($n = 10$) strongly disagreed. A statistical significance was observed ($p = 0.047$) between the level of education and the willingness for pet owners to go out of their way to collect compounded medicine, indicating that pet owners with a higher level of education are more willing to go out of their way to collect compounded medication than those with lower levels of education. Forty-seven percent ($n = 108$) of pet owners agreed, and 25% ($n = 57$) strongly agreed, that they would be willing to pay over and above the selling price of the prescription drug itself to have medicine specifically compounded for their pets. Eighteen percent ($n = 43$) neither agreed nor disagreed, 7% ($n = 17$) disagreed and 3% ($n = 7$) strongly disagreed.

Fifty-three percent ($n = 122$) of pet owners agreed, and 22% ($n = 50$) strongly agreed, that they would be more willing to go to a community pharmacist for advice regarding their pet if they can be sure they have the knowledge and skills. Figure 3.23 shows the number of pet owners who agreed or disagreed with this statement. When analysing the level of education and whether pet owners would be more willing to go to a community pharmacist for advice if they can be sure they have the knowledge and skills, a statistical

significance was observed (p = 0.008) indicating that pet owners with a higher level of education are more willing to ask a pharmacist for advice.

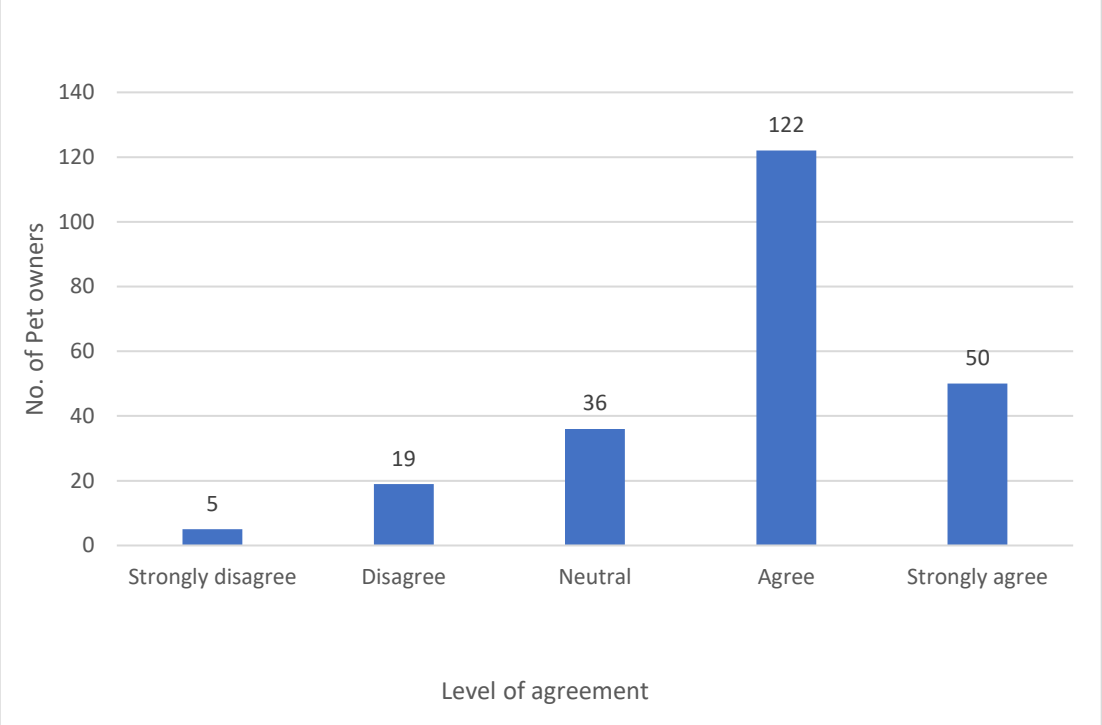

Figure 3.23: Pet owner's willingness to go to a community pharmacist for advice regarding their pet if they can be sure pharmacists have the knowledge and skills (N=232)

Fifty-seven percent (n = 133) would like to be able to ask the community pharmacist for advice on conditions pets suffer from. Twenty-five percent (n = 59) were not sure while 13% (n = 31) would not be willing to ask the pharmacist for advice. Four percent (n = 9) indicated that they already ask the community pharmacist for advice regarding their pets. A statistically significant difference (p = 0.002) was observed when analysing age and willingness to ask a community pharmacist for advice indicating that the younger generations would like to be able to ask the community pharmacy for advice more than the older generation.

The majority of pet owners (83%, n = 193), would like community pharmacies to stock veterinary medicinal products. Figure 3.24 shows the type of services pet owners would like community pharmacies to offer. Five percent (n=12) suggested other services including stocking veterinary medicinal products that are commonly used or on order by clients and having microchip readers in case of a lost pet. It was also suggested that since community pharmacies are more accessible, they can provide advice in certain cases as in allergies. Another suggestion was that it would be beneficial to have community pharmacists offer support on over-the-counter medication for minor issues.

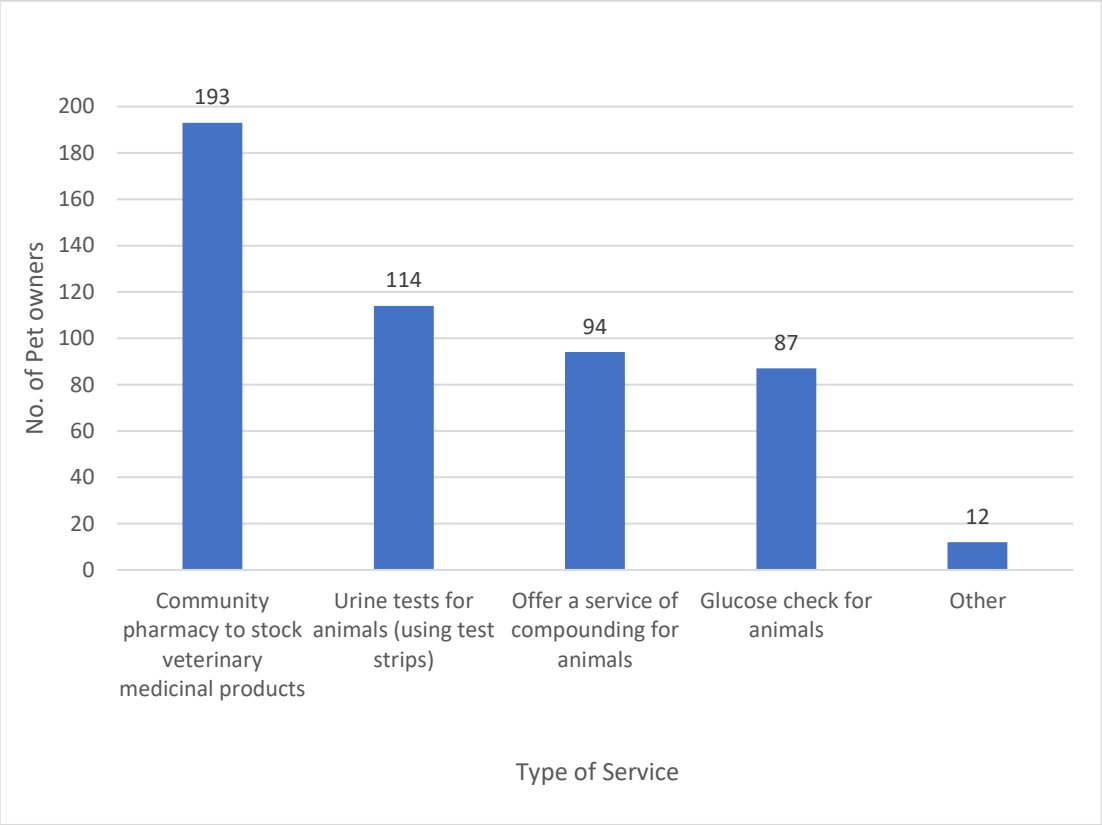

Figure 3.24: Services pet owners would like to see offered by a community pharmacy (N=232)

3.2. Part I (Phase II): Training Programme for Pharmacists in Veterinary Pharmaceutical Sciences

Phase II includes the development and validation of a training programme for pharmacists in veterinary pharmaceutical sciences.

3.2.1. Training Programme Validation Delphi Round I and Round II

Eight individuals from different areas of expertise were invited to participate in the validation exercise and all accepted. Six of the experts were Maltese and 2 were foreign. Six of the participants were female, and two were male. Eight participants took part in Delphi Round I.

The training programme received positive comments and feedback from the panel of experts. The results for the first round Delphi items are summarised in Table 3.3. Nine aims or learning outcomes (6%) failed to reach consensus in Round I. Six learning outcomes were from the area of veterinary disease states, and one aim and two learning outcomes from the area of veterinary pharmacotherapy (Appendix 6).

Changes in the original questionnaire which included omissions, re-wording and re-structuring were made after gathering feedback from Delphi round I. The changes made to the aims and learning outcomes may be found in Appendix 7.

Table 3.3: Delphi Round I consensus rates

		Number of aims and learning outcomes reaching consensus for inclusion as 'important'	Number of aims and learning outcomes not reaching consensus
Veterinary disease states	**Aims**	4	0
	Knowledge and Understanding	24	6
	Skills	12	0
Veterinary Pharmacotherapy	**Aims**	8	1
	Knowledge and Understanding	49	0
	Skills	18	2
Regulation of Veterinary Medicinal Products	**Aims**	6	0
	Knowledge and Understanding	8	0
	Skills	2	0

The modified aims and learning outcomes of the training programme all reached consensus following Delphi Round II. The training programme for pharmacists in veterinary pharmaceutical sciences was considered to be validated.

3.2.2. A Training Programme for Pharmacists in Veterinary Pharmaceutical Sciences

The training programme developed is intended for pharmacists who would like to develop skills and competencies in veterinary pharmaceutical sciences. It provides a comprehensive overview on the most important aspects of veterinary pharmacy. The training programme focuses on three main areas, namely (1) veterinary disease states; (2)

veterinary pharmacotherapy and (3) legal and regulatory considerations in veterinary pharmacy practice. Attributed to each of the areas is a validated list of aims and learning outcomes. The learning outcomes were divided into knowledge and understanding, and skills.

The information on veterinary disease states provides details on ten common disease states affecting companion and food-producing animals. This includes their pathology, signs and symptoms, diagnosis, pharmacotherapeutics and prognosis. It also provides an overview of how these conditions relate to the human equivalent. Parasite infestations and antimicrobial resistance and their impact on public health are also discussed. Veterinary disease states include (i) behavioural disorders, (ii) pain management, (iii) endocrine disorders, (iv) renal disorders, (v) cardiovascular disorders, (vi) gastrointestinal disorders, (vii) respiratory disorders, (viii) dental disorders, (ix) ophthalmic disorders and (x) dermatological conditions (Appendix 8).

The section on veterinary pharmacotherapy includes the pharmacotherapy options for the ten common disease states affecting companion and food-producing animals. The most important aspects of pharmacotherapy for the common disease states and how these relate to the human equivalent are discussed. Pharmacodynamic and pharmacokinetic differences that influence drug absorption, distribution, metabolism and excretion are emphasised. Challenges encountered while administering medication, managing conditions, monitoring progression of diseases and monitoring for side-effects of medications are highlighted. The off-label use of human medicinal products to treat diseases in companion animals is highlighted. The potential risks of using human OTC

products in companion animals are emphasised. An introduction to pharmacotherapy in food-producing animals, equine species and exotic animals is included.

An introduction to the regulation of veterinary medicinal products and its historical background is presented. The similarities and differences between the regulation of human medicinal products and veterinary medicinal products are discussed. This includes quality, safety and efficacy with emphasis on food-producing species. Key differences in the regulation between veterinary and human medicinal products are presented, with emphasis on demonstrating the safety of any residues, in food, from medicinal products that are administered to food-producing animals. The objectives and importance of regulation in the pharmaceutical field and how it impinges on the practice of veterinary pharmacy are highlighted (Appendix 8).

3.3. Part 2: Resources Required for a Regulatory Entity specialised in human medicines to extend its services to veterinary medicines

The results of the analyses of the regulatory framework for veterinary medicinal products are reported in this section. The identification of resources of different EU National Competent Authorities that regulate veterinary medicinal products are reported. The proposal for a support office within a regulatory entity specialised in human medicine that extends its services to veterinary medicinal products is reported.

3.3.1. Analysis of the Regulatory Framework

This section reports the results for the analysis of regulations governing veterinary medicinal products.

Directives must be transposed into national law. Gaps in the National Laws governing veterinary medicinal products were identified by comparing S.L.437.47 to Directive 2001/82/EC. Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products was implemented in 2001. The Directive was amended five times since (The European Parliament and the Council of the European Union, 2001a). S.L437.47 was amended three times.[24] The amendments are described in Appendix 9.

The analysis showed that during the transposition of Directive 2001/82/EC into National Law, thirty-four articles from the Directed were not transposed into S.L. 437.47. In four instances, there were inaccuracies in the cross-referencing. Articles within Directive 2001/82/EC were transposed into Regulations in S.L. 437.47. There are no corresponding regulations for Articles 36 – Article 39 in S.L.437.47. Articles 36 – Article 39 in Directive 2001/82/EC concern the mutual recognition procedure and decentralised procedure and were included following an amendment to the Directive. This constitutes an example of missing regulations. An example of an inaccuracy in cross-referencing includes: Article 12(3)(l) in Directive 2001/82/EC refers to Articles 58 and 61. Articles 12, Article 58 and Article 61 were transposed into Regulations 12, 51 and 55 respectively in S.L.437.47. In S.L. 437.47, Regulation 12(3)(l) refers to Regulations 53 to 55.

Regulation (EU) 2019/6 was compared to Directive 2001/82/EC to identify changes that were made in the new regulation (The European Parliament and the Council of the European Union, 2001a; The European Parliament and the Council of the European

[24] Ministry for Justice, Culture and Local Government. Subsidiary Legislation 437.47 Veterinary Medicinal Products Regulations [Internet] Malta: The Ministry 2004: 1-103 [cited 2020 May 21]. Available from: http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10983&l=1.

Union, 2019). In Regulation (EU) 2019/6 the validity of the marketing authorisation has been increased to an indefinite period as opposed to a period of five years. The regulation states that the Agency shall establish a Union database for veterinary medicinal products and includes information that must be included. There is more detail on the procedures of refusal of a marketing authorisation including the refusal of a marketing authorisation for antimicrobial treatment that is reserved to treat certain infections in humans. The Commission will designate antimicrobials or groups of antimicrobials that are reserved for the treatment of infections in humans.

Annex I in Directive 2001/82/EC describes "the chemical, pharmaceutical and analytical standards, safety and residue tests, pre-clinical and clinical trials in respect of testing of veterinary medicinal products." (The European Parliament and the Council of the European Union, 2001a) Annex I in Regulation (EU) 2019/6 describes the requirement for information relating to the legal basis for the marketing authorisation, the applicant, identification of the medicinal product, manufacturing and pharmacovigilance information, veterinary medicinal product information and other information in the application of a marketing authorisation . In Regulation (EU) 2019/6 the requirements for the technical documentation necessary for demonstrating quality, safety and efficacy of veterinary medicinal products is laid down in Annex II (The European Parliament and the Council of the European Union, 2019). There have been no changes in the content of Annex II. The articles within Directive 2001/82/EC have been reshuffled in Regulation (EU) 2019/6. Annex IV of Regulation 2019/6 is a correlation table that lists all the articles in Directive 2001/82/EC and their corresponding location in Regulation (EU) 2019/6.

Dossier Requirements

The composition of the Dossier required for the application of a marketing authorisation for veterinary medicinal products and human products are similar. The Dossier for application of a marketing authorisation for veterinary medicinal products consists of four parts. Part 1 is always required and constitutes the administrative information. Part 2 consists of chemical, pharmaceutical and biological documentation. Part 3 and 4 include safety and residues documentation, and the pre-clinical and clinical documentation respectively.[25]

The common technical document, or dossier, for human medicinal products is composed of five modules. Module 1 contains administrative, regional or national information. Module 2 consists of high-level summaries namely the Quality Overall Summary, the Non-clinical Overview / Summaries, and the Clinical Overview / Summaries. Module 3 provides chemical, pharmaceutical and biological documentation. Documentation regarding toxicological and pharmacological tests on active substances and finished products are provided by the non-clinical study reports in Module 4. Module 5 contains data about the clinical trials performed on the drug/medicinal product.[26]

The content of the dossier is laid down in Annex I of Directive 2001/82/EC for veterinary medicinal products, Annex 1 of the Directive 2001/83/EC for human medicinal products and Annex II of Regulation 2019/6 (The European Parliament and the Council of the

[25] European Commission (EC). Notice to applicants Volume 6B Veterinary Medicinal Products: Presentation and content of the dossier [Internet]. Belgium: European Commission; 2015 [cited 2020 May 28]. Available from: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-6/b/nta_volume_6b_2015_.pdf.

[26] European Commission (EC). Notice to applicants Volume 2B Medicinal Products for Human Use: Presentation and content of the dossier Common Technical Document [Internet]. Belgium: European Commission; 2008 [cited 2020 May 28]. Available from: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/b/update_200805/ctd_05-2008_en.pdf.

European Union, 2001a; The European Parliament and the Council of the European Union, 2001b; The European Parliament and the Council of the European Union, 2019).

The format of Annex 1 of Directive 2001/82/EC is different to that for human medicinal products. Despite the different format the information laid out is similar. Annex I is divided into four titles:

i. Title I describes "the standardised requirements for applications for veterinary medicinal products other than immunological veterinary medicinal products."
ii. Title II describes "the standardised requirements for applications for immunological veterinary medicinal products."
iii. Title III describes "specific types of marketing authorisation dossiers and requirements."
iv. Title IV describes "the dossier requirements for particular types of veterinary medicinal products."

In Title I, the introduction to general principles are the same for both veterinary and human medicinal products. The chemical, pharmaceutical and biological information include information on the active substances, excipients, manufacturing methods, finished product, container closure systems and stability studies and are common requirements for both human and veterinary medicinal products. Safety and residue, single and repeat-dose toxicity studies, carcinogenicity and reproductive and developmental toxicities are required in both veterinary and human medicinal products. Veterinary medicinal products have additional requirements for studies to be carried out in food-producing animals. Part 4 deals with the pre-clinical and clinical studies. Pre-clinical studies are required to establish the pharmacological activity and the tolerance of

the product. These include pharmacodynamics, pharmacokinetics and the development of resistance and tolerance in target species (The European Parliament and the Council of the European Union, 2001a). The requirements for what is reported for the clinical studies is similar to that found in human medicinal products.

Title II describes the standardised requirements for applications for immunological veterinary medicinal products and follows the same format as Title I. Title III includes the requirements for specific marketing authorisation applications. These include generic medicinal products, similar biological veterinary medicinal products, well-established veterinary use, combination products, applications in exceptional circumstances and mixed marketing authorisation applications. All of these are also present in Annex I for human medicinal products (The European Parliament and the Council of the European Union, 2001a). Requirements for herbal medicinal products are only found in Annex I for human medicinal products (The European Parliament and the Council of the European Union, 2001b).

Title IV deals with requirements for particular veterinary medicinal products and includes immunological products using the concept of a vaccine antigen master file and a multi-strain dossier, and homeopathic products (The European Parliament and the Council of the European Union, 2001a). Immunological and homeopathic products are also found Annex 1 for human medicinal products (The European Parliament and the Council of the European Union, 2001b). Annex I in 2001/82/EC Title II is dedicated to immunological veterinary medicinal products and is not included in 2001/83/EC.

The "Notice to Applicants" has been prepared by the European Commission, in consultation with the competent authorities of the Member States and the European Medicines Agency. Volume 6B gives guidance to applicants for marketing authorisations for veterinary medicinal products on the presentation of the data requirements and summaries of the dossier.[26] Volume 2B provides guidance for the compilation of dossiers for applications for European marketing authorisations and is applicable for the centralised procedure and national procedures, including mutual recognition and decentralised procedures for human medicinal products.[27]

3.3.2. National Competent Authorities within the EEA

There are 31 NCAs within the EEA. In fifteen Member States, the same NCA regulates both veterinary and human medicinal products. Table 3.4 outlines the Human and veterinary medicinal products fall under the remit of different NCAs for sixteen Member States, or countries, within the EEA (Table 3.4).

[26] European Commission (EC). Notice to applicants Volume 6B Veterinary Medicinal Products: Presentation and content of the dossier [Internet]. Belgium: European Commission; 2015 [cited 2020 May 28]. Available from: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-6/b/nta_volume_6b_2015_.pdf.

[27] European Commission (EC). Notice to applicants Volume 2B Medicinal Products for Human Use: Presentation and content of the dossier Common Technical Document [Internet]. Belgium: European Commission; 2008 [cited 2020 May 28]. Available from: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/b/update_200805/ctd_05-2008_en.pdf.

Table 3.4: The regulation of veterinary and human medicinal products by NCAs within the EEA

Same NCA for Human and Veterinary medicinal products	Different NCA for Human and Veterinary medicinal products
Austria	Bulgaria
Belgium	Croatia
Denmark	Cyprus
Estonia	Czech Republic
Finland	France
Greece	Germany
Iceland	Hungary
Ireland	Italy
Luxembourg	Latvia
The Netherlands	Lichtenstein
Norway	Lithuania
Poland	Malta
Slovenia	Portugal
Spain	Romania
Sweden	Slovakia
	United Kingdom

3.3.3. Validation and Reliability Testing of 'Identification of Resources of Different National Competent Authorities' Questionnaire

The aim of the NCA-Q was to identify the resources of different NCAs that regulate veterinary medicines with respect to assessment of veterinary medicines and medicines information. The NCA-Q was disseminated to 31 NCAs that regulate veterinary medicinal products with the EEA.

Six validation members completed both rounds of the validation process of the questionnaire by rating the questions proposed for the 3 domains of relevance, clarity and structure and layout (Appendix 10).

In Round I, one question and one statement (6%) obtained an I-CVI below the 0.83 threshold and were flagged for omission or revision. Both were in Section A. Four questions (13%) obtained an I-CVI at the required threshold but additional comments were provided. Feedback from the expert validation panel was deemed important and the comments were incorporated (Appendix 9). Ave-CVI outputs were calculated at 0.98, 0.97 and 0.98 for the validation domains of relevance, clarity, and structure and layout respectively for NCA-Q. This further supports the robustness of the questionnaire.

Following modifications in Round I (Appendix 11), all the questions or statements obtained an I-CVI of 1.00 and Ave-CVI of 1.00 in Round II. These values confirmed that NCA-Q was validated. Intra-subject reliability was upheld across the sections of the questionnaires. The NCA-Q can be found in Appendix 12.

3.3.4. Results from the Identification of Resources of Different National Competent Authorities Questionnaire

The NCA-Q was disseminated to 31 NCAs within the EEA. Ten NCAs compiled the questionnaire.

In addition to regulating veterinary medicinal products, 70% (n = 7) of the NCAs regulate homeopathic products and 60% (n = 6) regulate herbal medicinal products. Figure 3.25 shows the areas regulated by the different NCAs.

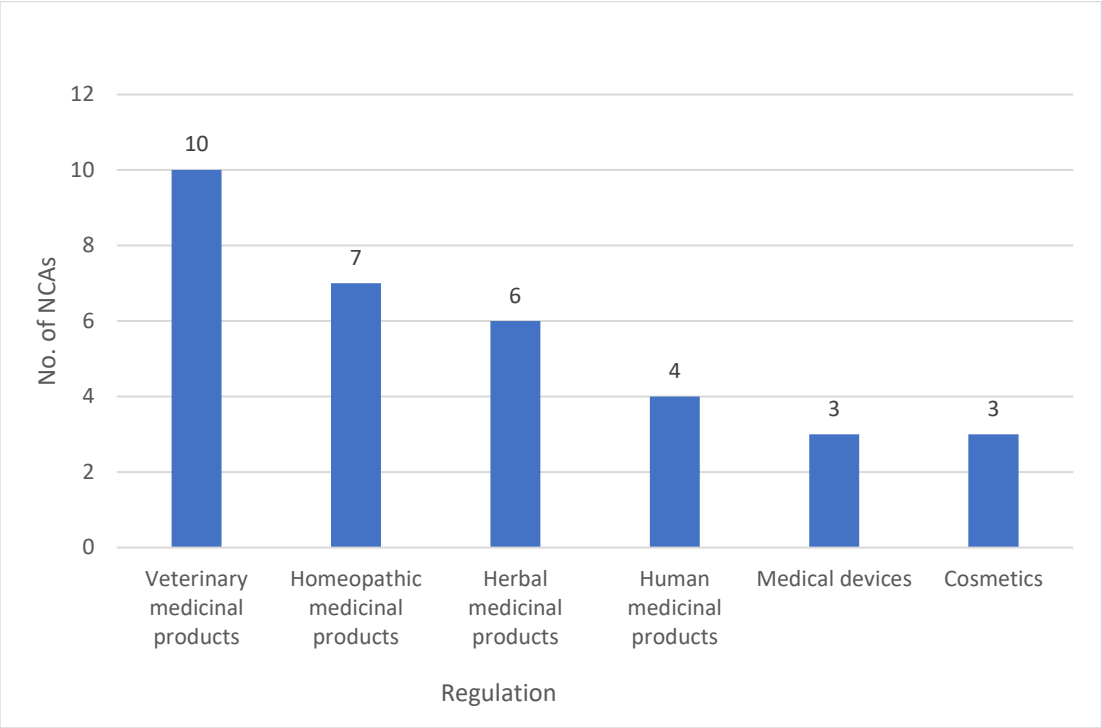

Figure 3.25: The different areas that fall under the remit of the NCAs analysed (N=10)

Participants were asked to identify which services were offered by their NCA. Ninety percent (n = 9) indicated that the NCA offers a service of monitoring safety of medicines. Eighty percent (n = 8) of respondents indicated that the NCA is involved in the granting and withdrawal of licenses, and processes variations to the marketing authorisation, and in conducting inspections. Seventy percent (n = 7) reported that the NCA offers regulatory advice or monitors the sales of antimicrobial agents. Figure 3.26 includes all the services given by the NCAs analysed.

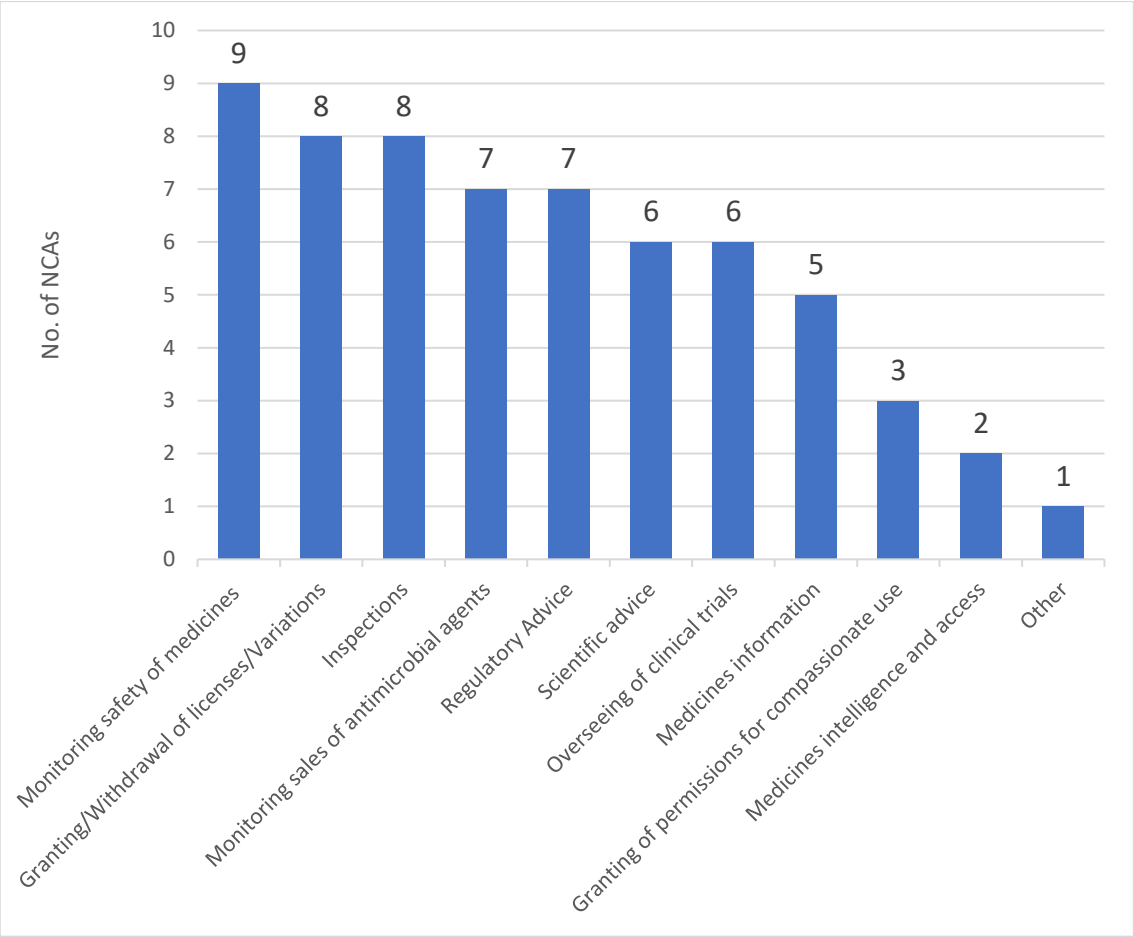

Figure 3.26: The services given by the NCAs analysed (N=10)

Sixty percent (n = 6) of respondents indicated that the NCA does not regulate both veterinary and human medicinal products. Sixty percent (n = 6) of respondents indicated that the services offered by the NCA for human medicinal product are the same as those offered for veterinary medicinal products. One respondent stated that additional requirements are in place for inspections of manufacturers for veterinary medicinal products. The NCA was responsible for granting Manufacturing Importation Authorisation for medicinal products. Another respondent indicated that in addition to human medicines, the NCA licenses distributors and provides export licenses and batch approval certificates for vaccines for veterinary use. This NCA also performs the assessment of feed additives. One respondent indicated that the services are different due

to different implementing rules. Another respondent indicated that the services provided are different due to less staff available for the rendering of veterinary services.

Participants were asked to indicate whether there is a dedicated department that offers services solely for the veterinary sector. Seventy percent (n = 7) indicated that there is a separate unit/department. Thirty percent (n = 3) reported that the NCA did not have a dedicated unit or department. Respondents were asked to provide a brief description of the organisation of those offering services in the sector of veterinary medicinal products if the NCA did not have a dedicated department. One respondent indicated that the entity was small, and the staff were multitasking. Another respondent indicated that most units/departments within the NCA work in an integrated manner with both human and veterinary medicinal products. One respondent indicated that different NCAs are responsible for different services. The Office for Registration of Medicinal Products, Medical Devices and Biocidals is responsible for issuing marketing authorisations (MA) and pharmacovigilance, the Chief Pharmaceutical Inspectorate conducts inspections of human and veterinary medicinal product manufacturers and for granting import authorisation, and the National Veterinary Inspection is responsible for veterinary medicinal products that are on the market.

Participants were asked whether the personnel are specifically trained in the area of veterinary medicines to be able to provide services within this sector. Ninety percent (n = 9) of the respondents indicated that the personnel are specifically trained in the area of veterinary medicines while 10% (n = 1) specified that personnel are not specifically trained in this area.

Respondents were asked to specify the areas of expertise of personnel within a unit or department that offers services for the veterinary sector. The areas of expertise selected by the respondents were veterinary medicine, pharmacy and pharmacology as indicated by 100% (n = 10), 80% (n = 8) and 80% (n = 8) respectively. Other areas of expertise included epidemiology, as indicated by 11% (n = 1) of respondents. Figure 3.27 below shows the areas of expertise of personnel offering services for the veterinary sector.

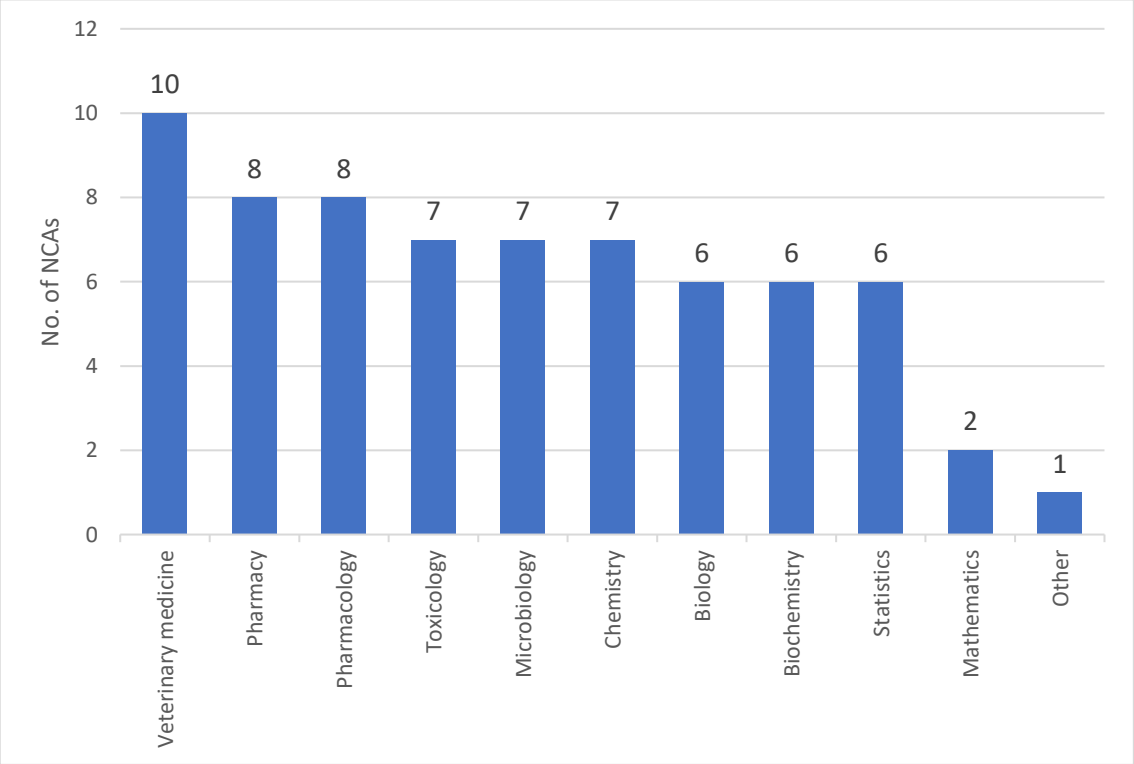

Figure 3.27: The areas of expertise of personnel within a unit or department that offers services for the veterinary sector (N=10)

Respondents were asked to estimate the percentage of the total workload that concerned veterinary medicinal products from different activities that are carried out by the NCA. Two respondents indicated that for granting/withdrawing of licences/variations, monitoring the safety of medicines and monitoring the sales of antimicrobial agents, greater than 90% of the workload concerns veterinary medicinal products. Two respondents claimed that for the granting/withdrawing of licenses/variations between 60

and 70% of the workload concerns veterinary medicinal products while one respondent indicated that 50% of the workload concerns veterinary medicinal products. Figure 3.28 gives an overview of the workload concerning veterinary medicinal products.

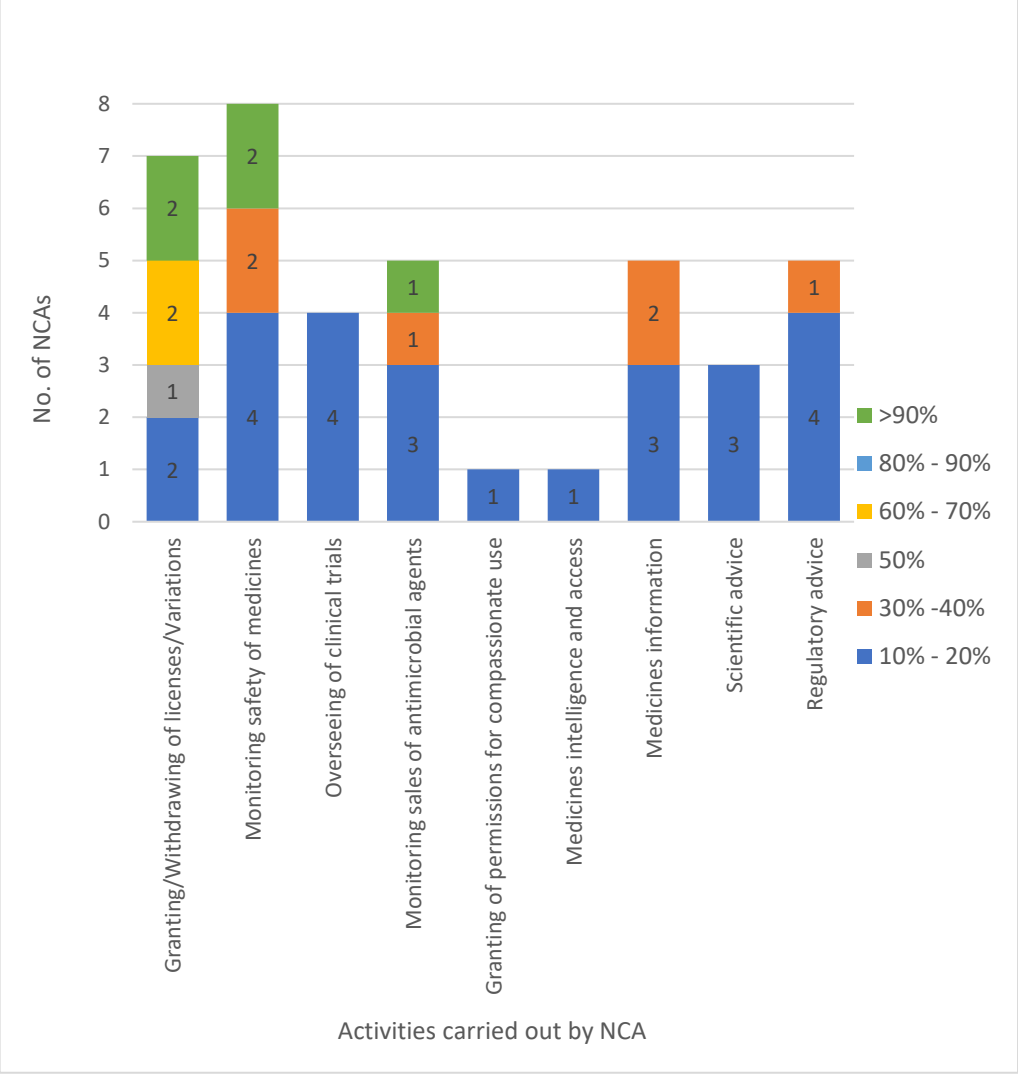

Figure 3.28: Overview of the workload concerning veterinary medicinal products (N=10)

Eighty percent (n = 8) of the respondents claimed that the NCA performed assessments of veterinary medicinal products while 20% (n = 2) do not. The participants were asked to identify for which types of authorisations assessments were carried out. Eighty-nine percent (n = 8) of respondents indicated that the NCA performs assessments for mutual recognition procedures, decentralised procedures and national authorisations. Sixty-

seven percent (n = 6) claimed that the NCA performs assessments for central authorisation procedures. One respondent indicated that marketing authorisations did not fall under the remit of their entity.

Eight participants answered the question concerning assessment of veterinary medicinal products. All respondents (n = 8) indicated that the NCA performs assessments for generic products and biological medicinal products. Eighty-eight percent (n = 7) claimed that the NCA performs assessments for similar biologicals, vaccines, immunological products, and homeopathic medicinal products. Figure 3.29 shows the types of medicinal products for which assessments are carried out.

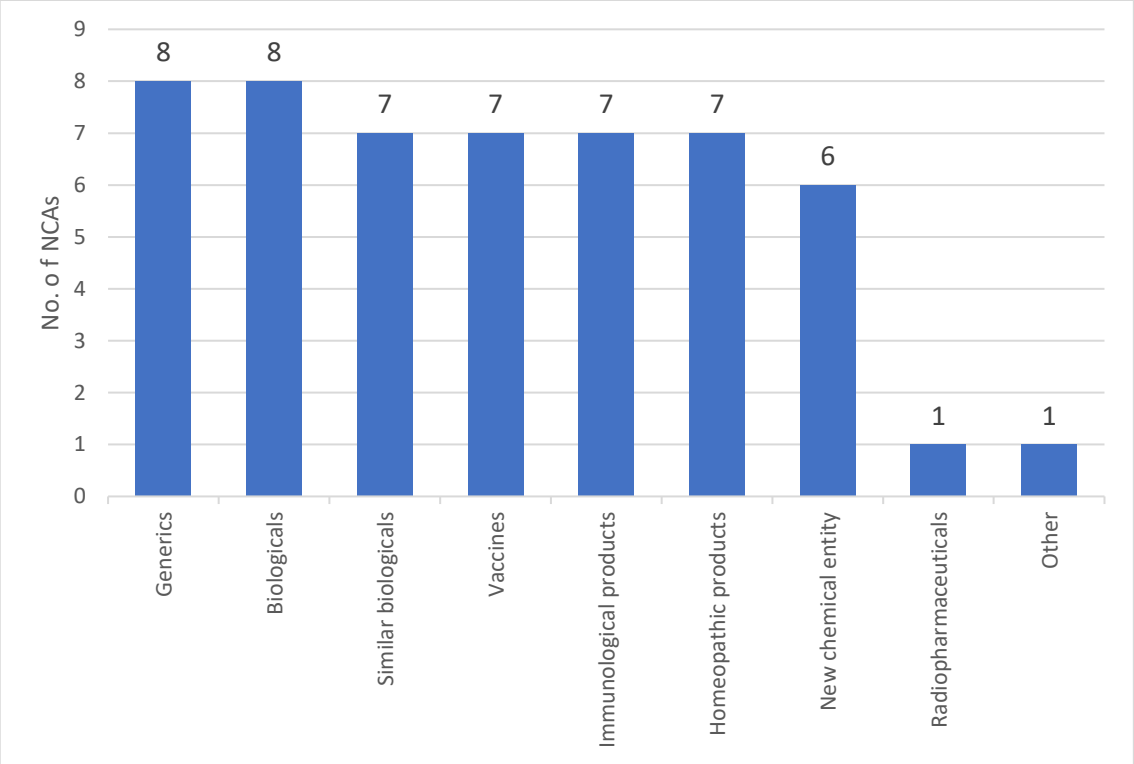

Figure 3.29: The types of medicinal products for which assessments are carried out by the different NCAs (N=8)

Eighty-eight percent (n = 7) of respondents claimed that assessments for veterinary medicinal products are carried out by assessors solely dedicated to assessing veterinary medicinal products, while 13% (n =1) are not. Participants were asked whether assessors required any prior qualifications or training in veterinary therapeutics to be able to assess veterinary medicinal products. Fifty-seven percent (n = 4) indicated that prior qualifications or training were required while 43% (n = 3) claimed that it depended on the type of assessment. Justifications for prior qualifications/training included that the work is complex, and prior training is required since it is a very specific area even when qualified in fields of veterinary sciences. Assessors specialised in veterinary medicine focus on part IV (pre-clinical and clinical trials) while other parts are assessed by assessors working in both human and veterinary medicinal products. One respondent indicated that the assessments of veterinary medicinal products are carried out by independent institutions.

Respondents were asked to indicate whether training for assessment of veterinary medicinal products was given by the NCA and to identify the type of training given. Seventy-five percent (n = 6) of respondents claimed that training was provided by the NCA, while 25% (n = 1) indicated that the NCA did not provide training. The respondents (n = 7) claimed that the NCA provided internal training, specific courses/conferences and training provided by other assessors. Eighty-six percent (n = 6) claimed that the external training was provided and fourteen percent (n = 1) indicated that training is given via the EU Network Training Centre (EU NTC and mostly, train on the job.

Training areas were claimed to be dependent on the expertise required for the specific part of the dossier, the job description and responsibilities. One respondent claimed that assessors must be trained in regulatory sciences and public administration. Another respondent reported that training areas included quality, safety and residues.

Seventy-one percent (n = 5) indicated that the NCA does not use external experts to assess veterinary medicinal products while 29% (n = 2) indicated that the NCA makes use of external experts. External experts carry out assessments for quality, safety and toxicology. Reasons for using external experts included that the required expertise is not available within the NCA or no adequately trained personnel available. It was reported by one NCA that the workload was sometimes too heavy and external experts were used to provide additional help. In some cases, the workload was not high enough to require someone solely dedicated to that task. One respondent indicated that that member state had a governmental institute for toxicology.

Participants were asked whether the NCA offered a service of medicines information for veterinary medicinal products and to briefly provide a description. Fifty percent (n = 5) claimed that the NCA offers a service of medicines information for veterinary medicinal products while 50% (n = 5) indicated that the NCA did not. The service of medicines information varied between respondents. Public access to a database for veterinary medicinal products was reported by one respondent. Another respondent claimed that the NCA provides general information on the website but no information on individual products was given to the general public. A common medicines information unit for both human and veterinary medicinal products was also reported by one NCA. It was also claimed that the NCA was the main contact point for questions related to veterinary

medicinal products. Ten percent (n=1) indicated that the NCA publishes web pages with scientific/regulatory/legislative information, issue of bulletins, pamphlets, and a basic information booklet for veterinary medicinal products.

Seventy percent (n = 7) of respondents indicated that the need for prior qualifications and training depend on the type of service offered. Thirty percent (n = 3) claimed that qualifications and training are required. One respondent claimed that knowledge of veterinary medicinal products and regulatory aspects are required. The three respondents who indicated that the type of training depends on the service reported that training required depends on the task with the processes of providing this service. One respondent indicated that personnel qualified in different areas are involved in different aspects of the processes. According to one respondent, if necessary, collaboration with external medicine specialists may be sought.

Seventy (n = 7) of respondents claimed that training is not provided by the NCA while 30% (n = 3) indicated that the NCA does provide training. The type of training given was reported to be internal training, specific courses/conferences, external training and training via the EU-NTC.

Respondents were asked to identify sources used to provide the requested information. The 10 NCAs that compiled the questionnaire indicated that product databases, websites, regulations, decisions, guidelines, and scientific literature were identified as sources used. EU and national sources and external experts were used as sources of information.

Eighty percent (n = 8) of respondents claimed that the NCA communicates, cooperates or collaborates with other NCAs that do not regulate veterinary medicinal products. Other NCAs were identified to be responsible for human medicines (88%, n=7), medical devices (38%, n=3), homeopathic products (38%, n=3), herbal medicinal products (25%, n=2), cosmetics (25%, n=2) and biocides (13%, n=1).

Participants were asked to identify areas of collaboration/cooperation with other NCAs. Seventy-five percent of respondents (n = 6) claimed that the NCAs consulted with each other and invited each other's staff as observers/additional attendees when attending meetings/seminars or conferences. The NCAs collaborated to achieve good regulatory practices in the field of medicine. Sixty-three percent (n = 5) indicated that the NCA included members of the NCA responsible for human medicines for courses organised by the EU NTC for veterinary medicinal products and vice versa. Fifty percent (n = 4) reported that other NCAs help with assessments of veterinary medicinal products. Thirty-eight percent (n = 3) claimed that other NCAs collaborated by sharing correspondence in relation to common areas of interest and comment on each other's standard operating procedures. Access to network infrastructure, cooperation within the EU network and EU (HMA or EMA) committees, counterfeit medicine product (in terms of VMP) and strategy of preventing of antimicrobial resistance were reported as other means of collaboration and cooperation.

3.3.5. Proposal for Veterinary Medicines Support Office

The proposal is for the setup of a support office within a regulatory entity specialised in human medicinal products that extend services to veterinary medicinal products. Services considered were the assessment of veterinary medicinal products and medicines

information. The proposal drafted (Appendix 13) was based on data and feedback obtained from the analysis of the regulatory framework and NCA-Q. The data was supplemented by material from published literature and information that is available for the public. The proposal outlines the purpose for a support office. One of the main roles of the support office is to perform assessments of veterinary medicinal products. During an assessment of a medicinal product, it is determined whether the necessary quality, safety and efficacy requirements are met and that it has a positive benefit-risk ratio for its intended use.[28] The proposal includes an overview of the different types of assessment and expertise required. The use of external experts is also included. The involvement of the support office in the EMA is highlighted.

The role of the support office in providing medicines information is included. The proposal includes different services it may offer in this regard. Training is required for personnel specialised in human medicines to offer services for veterinary medicines. The proposal gives an overview of the different types of training that may be employed. Areas of cooperation and collaboration with other national competent authorities, such as those regulating veterinary medicines are highlighted.

3.4. Dissemination of results

Two abstract submissions entitled 'Education and Training in Veterinary Pharmaceutical Sciences' and 'Pet Owner Perception of the Role of the Pharmacist in Animal Care' were accepted as a poster presentation at the International Pharmaceutical Federation (FIP) 2020 (Appendix 14).

[28] European Medicines Agency (EMA). Committee for Medicinal Products for Veterinary Use (CVMP) [Internet]. The Netherlands: EMA; 2020 [cited 2020 Jun 23]. Available from: https://www.ema.europa.eu/en/committees/committee-medicinal-products-veterinary-use-cvmp.

Chapter 4

Discussion

4.1. Veterinary Pharmacy: The Road to Excellence

Traditionally, human and animal medicine were viewed independently even though human and animal health are closely related. Animal patients are diverse and include companion animals, food-producing animals, captive animals and wildlife. Each group of animal patients have their unique health conditions but also share some health conditions with the human population (McDowell et al, 2017). Pets, or animal companions, develop chronic conditions such as thyroid disorders, diabetes, osteoarthritis and cardiovascular diseases. Pets are prescribed human medicines to be used off-label to treat where commercially available medications are not available (Bennet et al, 2018).

Animal companions are viewed as members of the family. This change in the mindset is altering the way animals are cared for (Young et al., 2017). From the perspective of animal care, the pharmacist is responsible to provide high quality pharmaceutical care and the provision of safe and effective medicine that equals that given to humans. From a regulatory perspective, there is a responsibility to provide an equal regard to protection and safeguarding of animal health as that of human or public health. This responsibility includes the regulation of veterinary medicinal products at a European and National level and the local collaboration between entities that regulate human and medicinal products to strive for excellence.

Pharmacists practising in the community setting may be presented with prescriptions for animal patients (Lust, 2003). In this study, fifty-one percent of pet owners claimed that they have been prescribed a medicine that needed to be purchased from a community pharmacy. Pharmacists indicated that they dispensed medicines for use in animals on a monthly basis while data obtained from veterinary surgeons, indicates that they prescribe

human medicines for use in animals on a weekly basis. It could be postulated that a reason for this discrepancy is that human medicines for use in animals are not solely purchased from a community pharmacy but may be available from veterinary clinics.

This study reveals that the perception of the role of the pharmacist in animal care is unfavourable. Pharmacists feel that they do not possess the competence in caring for veterinary patients. These findings are concordant with a local study carried out by Soler (2012) where pharmacists felt they were not very knowledgeable in the field of veterinary medicine. This shows that the perception of the pharmacist has not changed since 2012. Young et al., (2018) assessed the pharmacists' knowledge of core concepts of veterinary pharmacotherapy among 602 pharmacists by means of a questionnaire. With average overall scores between 29% and 35%, the study showed that pharmacists were unprepared to be involved in animal care due to a lack of understanding of veterinary pathophysiology, legal aspects of compounding and pharmacotherapy (Young et al., 2018). Lack of knowledge and confidence are preventing pharmacists from getting involved in veterinary pharmacy (Lust, 2009). This has also been reported in studies among pharmacists within the UK, USA, and Canada (O'Driscoll et al., 2014a; O'Driscoll et al., 2015; Frankel et al., 2016).

Veterinary surgeons and pet owners perceive the pharmacist as insufficiently skilled in the treatment and caring of animals. In this study, the pharmacist is perceived as not competent in caring for animal patients, unable to safely dispense and provide advice for animal prescriptions and unable to give advice for certain chronic conditions, seen in humans that are also seen in animals. The lack of trust towards pharmacists was perceived by fifty-two percent of veterinary surgeons and fifty-three percent of pet owners. This

indicates that trained pharmacists should strengthen their role with veterinary surgeons and pet owners. McDowell et al., (2017) investigated the views of veterinary surgeons and veterinary students, in New Zealand, on the role of the pharmacist supporting the veterinary surgeons with advice on veterinary medicines. The veterinary surgeons interviewed did not collaborate with pharmacists on a regular basis. Those not supporting the role of the pharmacist in animal care indicated that there are differences in metabolism between humans and animals that pharmacists are not knowledgeable about. According to the veterinary surgeons, pharmacists were not able to provide practical advice to pet owners to solve challenges of administration of medication to animals. The hesitation, among veterinary students, to collaborate with pharmacists may be attributed to the lack of awareness, among veterinary students, of the knowledge pharmacists possess regarding medicines and the role of the pharmacist within the healthcare system. (McDowell, et al., 2017). The veterinary surgeon's perception of the role of the pharmacist could possibly result in a lack of trust towards pharmacists and their contribution towards animal care.

Pharmacists are uniquely positioned to counsel pet owners and collaborate with veterinary surgeons to provide the best care for animal patients (O'Driscoll et al., 2014; Bennet et al, 2018). The concept of interdisciplinary collaboration to provide the best care for animals is one that was endorsed by veterinary surgeons, pharmacists and pet owners in this study. Despite the unfavourable perceptions, veterinary surgeons in this study feel that veterinary-pharmacist collaboration was important and beneficial to provide the best care for animals and access to medicine that is safe and effective. When analysing age of the veterinary surgeons and whether there is the need for interprofessional collaboration to provide the best care for animal patients, a statistically significant difference was observed ($p = 0.009$), indicating that the younger age groups

are more in favour of interprofessional collaboration. This may be due to the fact that younger generations are more accustomed to the culture of interdisciplinary collaboration (Nancarrow et al., 2013). It may also be postulated that experienced vets do not regard interdisciplinary collaboration as important. The age of the respondents was mostly in the lower age groups with little representation above the 40-49 years of age bracket. This result may be due to the small number of veterinary surgeons who compiled the questionnaire. Increasing the sample size may change the result obtained.

Pet owners would like to be able to ask the community pharmacist for advice and they would be more willing to go to a community pharmacist to ask about their pet if they can be sure that the pharmacist is knowledgeable and skilled in animal care. When analysing the level of education and willingness to ask a pharmacist for advice, a statistically significant difference was observed ($p = 0.008$). This indicates that pet owners with a higher level of education are more willing to ask a community pharmacist for advice if the can be assured of the pharmacist's competence. In a study carried out by O'Driscoll et al., (2014b) among twenty Irish and Scottish community pharmacies, it was reported that all Irish community pharmacists had been approached by members of the public seeking advice about the correct use of veterinary medicine. The situation among the Scottish community pharmacists is contrasting, with no members of the public asking the community pharmacist for advice (O'Driscoll et al., 2014b).

Results from this study indicate that veterinary surgeons, pharmacists, and pet owners would like community pharmacies to stock veterinary medicinal products. This was agreed on by eighty-three percent of pet owners, seventy-six percent of pharmacists and sixty-seven percent of veterinary surgeons. One can postulate that the current scenario

of access to veterinary medicinal products needs to be improved. The therapeutic need in veterinary patients is varied and the availability of veterinary medicinal products for all veterinary species and indications is small (Davidson, 2017). Access to veterinary medicinal products is a challenge that is also present within the UK, as few pharmacies stock veterinary medicinal products. From a total of 14,045 registered premises within the UK, in 2014, there were only twenty to thirty specialist veterinary pharmacies that only sold veterinary medicines (O'Driscoll et al., 2014a). The rest of the pharmacies did not cater for animal patients, or, at most, sold medication against fleas and worms. This is contrasted by pharmacies in Denmark and Sweden that dispense a high proportion of veterinary medicines. In Belgium and Ireland, rural pharmacies also dispense medicinal products for food-producing animals.[29] Community pharmacists are visited by those who incidentally own a companion animal on a daily basis (Evans, 2011; O'Driscoll et al., 2014a). Stocking veterinary medicinal products may help strengthen the role of the pharmacist with pet owners. Stocking and selling veterinary medicinal products sends the message that from a community pharmacy one can both purchase the medicine and obtain advice (Evans, 2011).

Community pharmacies are receiving an increased amount of prescriptions for veterinary patients (Young et al., 2017; McDowell et al., 2017). This study shows that forty-three percent of the veterinary surgeons prescribe human medicines for use in animals on a weekly basis, and twenty-four percent do so on a monthly basis. The length of practice of veterinary surgeons did not result in statistically significant differences when comparing it to the frequency of prescribing human medicinal products off-label for use

[29] Pharmaceutical Group of European Union (PGEU). PGEU Position Paper on proposal for a Regulation on veterinary medicinal products [Internet]. Belgium: PGEU; 2015 [cited 2020 Jun 13]. Available from: https://www.pgeu.eu/wp-content/uploads/2019/03/15-01-08E-PGEU-Position-Paper-on-Vet-Medicines-Proposal-FINAL.pdf.

in animals. This indicates that the number of years of practising as a veterinary surgeon does not affect these prescribing trends. The drugs of first choice to treat animal patients should always be authorised veterinary medicinal products. If there is no suitable authorised veterinary medicinal product for a specific condition in a particular species, veterinary surgeons may treat the animal patient using the 'Cascade'. In accordance with the prescribing cascade, veterinary surgeons may prescribe authorised human medicinal products off-label to treat animal patients if there are no suitable veterinary medicinal products for use in another species, or for a different indication for the same species. [30]

The main motivation behind prescribing human medicinal products for use in animals, according to veterinary surgeons in this study, is that the veterinary medicinal product required is not available. Other reasons included that the veterinary equivalent does not exist. These reasons seem to be in accordance with the prescribing cascade.[29] Fourteen percent of the veterinary surgeons prescribe human medicines as it is problematic for the pet owners to access a veterinary clinic or pharmacy. Community pharmacies are more accessible than veterinary pharmacies as the number of community pharmacies is much greater. Veterinary surgeons who see pets at home and not in a specific clinic, with access to medicinal products, may choose to prescribe a human medicinal product. Other reasons why veterinary surgeons are compelled to prescribe human medicinal products is that the products may not be available due to local shortage of medicinal products or the products are not authorised for selling within the country. Human medicinal products can be used off-label for use in animals. Human medicinal products are mostly purchased

[30] Royal College of Veterinary Surgeons (RCVS). Veterinary medicines [Internet]. UK: RCVS; 2020 [cited 2020 Jun 13]. Available from: https://www.rcvs.org.uk/setting-standards/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance/veterinary-medicines/.

from the community pharmacy which increases the involvement of the pharmacist in the treatment of animals.

Veterinary surgeons must take into consideration a number of factors when deciding on treatment options for their patients. The most challenging factors, as described in this study, that influence the choice of treatment is that the owners are not able to administer the formulation available and that the dosage form available is not appropriate for animal administration or the available doses are too large. This presents challenges of access to medicine.

Most pharmacists (64%) were not aware of the challenges veterinary surgeons face when deciding on treatment options for their patients. The data obtained shows that according to the pharmacists who were aware of the challenges veterinary surgeons face the main motivation is that the veterinary medicinal product required is not available, veterinary equivalents do not exist and it is difficult for pet owners to access a veterinary clinic or pharmacy. This data corresponds with the data obtained from VSP-Q. When analysing age and awareness of the challenges vets face when deciding on treatment options, a statistically significant difference was observed ($p=0.001$), indicating that younger pharmacists were not aware of these challenges. When analysing the length of practice in a community pharmacy and the awareness of the challenges veterinary surgeons face when deciding on treatment options a statistically significant difference was not observed ($p=0.055$). Pharmacists practising within the community were aware of the challenges veterinary surgeons faced when deciding on treatment options. Data shows that community pharmacists, irrespective of their age, are aware of the challenges faced by veterinary surgeons.

In this study, veterinary surgeons report that the biggest challenge pet owners face is that pets would not eat or swallow the medication prescribed followed by a lack of compliance to the treatment regimen. The majority of pharmacists (60%) were aware of the challenges pet owners faced when administering medication to their pets. According to pharmacists, the biggest challenges were that the pet would not eat or swallow the medication. This was followed by the medication dosing/administration being difficult or messy. Pet owners indicated that the biggest challenge was that pets would not eat or swallow the medication followed by the pet getting stressed. Administering medication is reported to be challenging for effective compliance. Bennett et al. (2018) reports that challenges to administration of medication include the pets injuring their owners, lack of palatability and refusing to swallow the tablets (Bennett et al., 2018).

Data from this study shows that only 10% of pet owners have been prescribed a medicinal product that needed to be compounded. Ninety-five percent of the pharmacists and 76% of the veterinary surgeons do not perform compounding. Compounding was performed by the veterinary surgeon, a pharmacist, or a veterinary technician amongst those who offer the service. The data suggests that in Malta, veterinary compounding is not a service that is commonly given to animal patients. In contrast, in a Guidance for Industry released by the US Food and Drug Administration, in 2015, it was reported that in the USA 75,000 pharmacies compound over 6 million veterinary prescriptions each year (Davidson, 2017). One can postulate that there is a need for veterinary compounding services in a community setting to improve access to medicines.

Compounding is the process by which a formulation is developed specifically tailored to the needs of an individual patient (Powers and Davidson, 2018). Veterinary

compounding services have the potential to improve access to medicines by alleviating challenges arising from administration of medication (Bennett et al., 2018; Gochenauer, 2019). The data from this study showed that a compounding service for animals was suggested as a service community pharmacists may offer by 57% of the veterinary surgeons, 55% of the pharmacists and 41% of pet owners. This study shows that pet owners are willing to go out of their way and pay over and above the selling price of the medication to obtain medication specifically compounded for their pet. Compounding medications carries a risk of serious harm and failure to achieve a therapeutic effect since they may be of poorer quality, inadequately prepared, contaminated, unstable and lack bioavailability in the target patient (Davidson, 2017). The practice of compounding is usually performed by pharmacists. Pharmacists are experts in the field of human drug therapy and pharmacology. Extrapolation to animal medical treatment is not without risk. Awareness of anatomical, physiological, metabolism and toxicological differences for animal patients will improve the safety and efficacy of compounded medicine (Davidson, 2017). Knowledge of compounding methods and regulation governing compounded medication, if any, improves the quality of compounded medicines for use in animals (Feldschuh, 2008; Davidson, 2017).

Findings from this study show that veterinary surgeons and pharmacists agreed that pharmacists should be trained in veterinary therapeutics. A local study by Soler (2012) had concluded that pharmacists wished to learn more about veterinary medicine. This study has shown that since 2012 the perception of the pharmacist in this regard has remained unchanged. Pharmacists dispensing medication for use in animals should be familiar with common disease states and comparative pharmacotherapy. Knowledge facilitates counselling, makes it more effective and improves animal care (Theberge and

Sehgal, 2016). There is the need to familiarise pharmacy students and pharmacists with veterinary medicinal products (Ceresia et al., 2009; Adrian et al., 2014). Historically, the educational curriculum in pharmacy has centred around the human as the centre of disease states (Lust, 2003). The growth seen in veterinary pharmacy practice has not been paralleled by an increase in pharmacist education in the areas of veterinary disease states, pharmacotherapy and legal and regulatory issues (Lust, 2003).

Studies have been carried out to identify different ways in which training in veterinary pharmaceutical sciences can be disseminated to pharmacists or pharmacy students to instil an appreciation towards veterinary medicine and the interdisciplinary collaboration between pharmacists and veterinary surgeons (Lust, 2003; Lust 2006; Adrian et al., 2014; O'Driscoll et al., 2015; Miller and Seghal, 2016). To help practising pharmacists develop new skills, the effect of an online continuing professional development course was assessed by Lust (2003). Lust (2006) also assessed the effectiveness of a short elective course that provided instruction on specific veterinary disease states and the human and veterinary medicinal products for their treatment. The inclusion of live animals for case studies was also investigated. Adrian et al. (2014) describes how exposure to a veterinary clinic setting exposes pharmacy students to the distinct prescription and administration of medicine to animal patients. Miller and Seghal (2016) report findings on the inclusion of a course, instructed by a veterinary surgeon, designed to expose pharmacy students to essential elements of the treatment of companion animals and then use this information to design client information sheets to be published on a website accessible to the public (O'Driscoll et al., 2015). The different training programmes have increased the confidence of practising pharmacists as well as their knowledge and skill in veterinary

pharmaceutical sciences (Lust, 2003; Lust, 2006; Adrian et al., 2014; O'Driscoll et al., 2015; Miller and Seghal, 2016).

A training programme in veterinary pharmaceutical sciences has been developed and validated in this study. The training programme focuses on three main areas namely veterinary disease states, pharmacotherapy and the regulation of veterinary medicinal products. Veterinary disease states included the ten most common conditions seen in animals, as described in literature and corroborated in this study. Each main area consists of a number of aims and learning outcomes. Suggestions for methods of training included short courses, study units or modules in a curriculum and placements in a veterinary clinic. The preferred method for 81% of the pharmacists was a training programme in the form of short courses followed by the inclusion of study units or module in the curriculum. The training programme developed in this study has been designed to provide guidance, to those disseminating the information, on what the most important aspects are to be discussed in order to achieve the required aims and learning outcomes. The delivery of the training programme may be in the form of a module/credits included in the curriculum or via a number of short courses with different courses targeting different aspects each achieving the aims and learning outcomes. Findings in this study also showed that training in veterinary pharmaceutical sciences may be obtained by incorporating placements in veterinary clinics. One may postulate that rotations in veterinary clinic may be more targeted towards pharmacy students. The University of Florida Veterinary Hospital Pharmacy offers both introductory and advanced pharmacy rotations throughout the academic year. At an introductory level, students practice in a hospital pharmacy setting for 80 hours. Advanced level rotations are available for

students during their fourth-year clinical practice experience.[31] The relationship between pharmacy and veterinary medicine is likely to improve animal care (Adrian et al., 2014). Increasing the veterinary surgeons' knowledge of a community pharmacist's training may lead to interprofessional trust and collaboration to improve veterinary patient safety and animal care (Bennet et al., 2018). Adrian et al, in 2014, investigated the effect of incorporating a veterinary clinical setting into a human-centred pharmacy programme to strengthen student appreciation and awareness towards veterinary medicine and increase the collaboration between pharmacists and veterinary surgeons. It was revealed that clinical rotations in a veterinary setting were valuable to the students both in terms of pharmacy education and their role as pharmacists. Another outcome from the rotation was how to effectively provide education to pet owners and increased their caring attitude and behaviours. Students appreciated the need to include pharmacists within the veterinary setting (Adrian et al., 2014).

An area that may not be familiar to pharmacists are the legal and regulatory issues governing veterinary pharmacy and how these relate to regulatory issues governing human medicines (Lust, 2004). The regulation of veterinary medicinal products was incorporated as one of the areas within the training programme developed in this study. This study also identified differences and similarities in these processes by comparing the regulations, processes and procedures involved in the authorisation of medicinal products. Data obtained from different national competent authorities in this regard was used to identify the resources required for an entity specialised in human medicines to extend its services to veterinary medicinal products. Services considered were the assessment of veterinary medicinal products and medicines information.

[31] UF Veterinary Hospitals. Pharmacy Rotations [Internet]. USA: UF Veterinary Hospitals; 2020 [cited 2020 Jun 12]. Available from: https://hospitals.vetmed.ufl.edu/pharmacy/pharmacy-rotations/.

In this study an analysis was performed comparing the European Directive governing veterinary medicinal products with the transposition into National Law to identify any gaps. During the course of this study, the regulations governing veterinary medicinal products were updated. As a result, the impact of the gaps identified in the current legislative framework were not assessed. Directive 2001/82/EC is to be repealed and will be replaced with Regulation (EU) 2019/6.[32] Directives must be transposed into national law for each of the member states. This has led to diverging transpositions which have resulted in different protection levels of animal and public health among member states. The function of the internal market has also been compromised. The European Commission has proposed a harmonised, innovative regulatory framework to improve the situation of the veterinary sector.[33]

Antimicrobial resistance is a complex challenge that threatens human and animal health (Kahn, 2017; White and Hughes, 2019). The new regulation aims to fight antimicrobial resistance by banning the prophylactic use of antibiotics in groups of animals, restricting the metaphylactic use, reserving certain antibiotics for treatment in humans only and obliging member states to collect data on the sale and use of antibiotics. Data collected from this study suggests that seventy percent of the respondents from NCAs that compiled the questionnaire already have systems in place that monitor the sales of antimicrobial agents. The Finnish Medicines Agency (FIMEA) has been monitoring the sales of

[32] European Medicines Agency (EMA). Implementation of the new Veterinary Medicines Regulation [Internet]. The Netherlands: European Medicines Agency; 2020 [cited 2020 May 25]. Available from: https://www.ema.europa.eu/en/veterinary-regulatory/overview/implementation-new-veterinary-medicines-regulation.

[33] DG Health and Food Safety: Animal nutrition, veterinary medicines. Safe and Effective Veterinary Medicinal Products [Internet]. Belgium: European Commission; 2020 [cited 2020 May 25]. Available from: https://ec.europa.eu/food/animals/health/veterinary-medicines-and-medicated-feed/veterinary-medicinal-products_en.

veterinary antimicrobial agents since 1995.[34] Estonia and Ireland monitor the sales of antimicrobial agents based on wholesalers' reports.[35,36] The European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) is a project that was started in 2010 with the aim of developing a harmonised approach for the collection and reporting of data related to the sales of antimicrobial agents in thirty-one European countries (EEA). The EMA publishes an annual report on the sales of veterinary antimicrobial agents.[37] The fight against antimicrobial resistance is one of the goals of the 'One Health' initiative. Approaches to combat antimicrobial resistance include the reduction of the use of antimicrobials in food-producing animals (White and Hughes, 2019). The One Health initiative advocates the use of a collaborative approach of multiple health science professions to attain optimal health for humans, animals and their shared environment (McEwan and Collignon, 2018; Barton Behravesh, 2019; Bright-Ponte et al., 2019; White and Hughes, 2019).

Annex I of Directive 2001/82/EC lays down the requirements of the dossier for the authorisation of veterinary medicinal products. Annex I of Directive 2001/83/EC lays down the requirements of the dossier for the authorisation of human medicinal products. The two dossiers were compared to identify any similarities and differences in the

[34] Finnish Medicines Agency (FIMEA). Consumption of veterinary antimicrobials [Internet]. Finland: FIMEA; 2018 [cited 2020 Jun 12]. Available from: https://www.fimea.fi/web/en/veterinary/consumption_of_veterinary_antimicrobials.

[35] State Agency of Medicines. Statistics on veterinary medicines [Internet]. Estonia: State Agency of Medicines; 2019 [cited 2020 Jun 12]. Available from: https://ravimiamet.ee/en/statistics-veterinary-medicines.

[36] The Department of Health and The Department of Agriculture, Food and the Marine. Ireland's first One Health Report on Antimicrobial Use and Antimicrobial Resistance. [Internet]. Ireland: The Department of Health and The Department of Agriculture, Food and the Marine; 2019 [cited 2020 Jun 12]. Available from: https://www.agriculture.gov.ie/media/migration/animalhealthwelfare/amr/nationalinterdepartmentalamrconsultativecommittee/OneHealthRptAntimicrobialUseResistance010219.pdf.

[37] European Medicines Agency (EMA). European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) [Internet]. The Netherlands: EMA; 2020 [cited 2020 Jun 11]. Available from:https://www.ema.europa.eu/en/veterinary-regulatory/overview/antimicrobial-resistance/european-surveillance-veterinary-antimicrobial-consumption-esvac.

requirements. The data obtained suggests that the despite the different structure of the dossier the information required for human and veterinary medicinal products is very similar in aspects related to administrative data, chemical, pharmaceutical and biological documentation and data from pre-clinical and clinical trials. Veterinary medicinal products require a separate section on safety and residues of pharmacologically active compounds. These are especially important when medication is given to food producing animals where humans consume products such as milk, eggs and meat.

Prior to issue a marketing authorisation for a veterinary medicinal product, each part of the dossier must be assessed to assess the safety, quality and efficacy of the medicinal product and ensures that the benefit-risk ratio is favourable.[38,39] Data collected from different NCAs suggests that the areas of the dossier that require specific expertise in veterinary medicine are the pre-clinical and clinical data in Part IV of the dossier. It was suggested that in these cases experts in veterinary medicine are tasked with carrying out the assessment of part IV. Parts of the dossier that are in common, such as quality and safety, may be assessed in an integrated fashion with an assessor assessing the same part in both human and veterinary products. The data obtained in this study suggests that despite the majority of the NCAs that compiled the questionnaire having a separate department or unit that offers services for the veterinary sector, it is not compulsory. The data indicates that in small entities the staff multitask and work in an integrated manner alternating between human and veterinary medicinal products. Expertise in veterinary medicine can be seen in all the NCAs that compiled the questionnaires. Experts in

[38] International Forum on Advancements in Healthcare (IFAH-Europe). The Marketing Authorisation Process for Veterinary Medicinal Products in Europe [Internet]. Belgium: IFAH-Europe; 2004 [cited 2020 Jun 17]. Available from: https://www.bft-online.de/fileadmin/bft/publikationen/IFAH-Europe-MarketAuth-brochure.pdf.

[39] Medicines Evaluation Board (MEB). Application Procedures [Internet]. The Netherlands: MEB; 2020 [cited 2020 Jun 17]. Available from: https://english.cbg-meb.nl/topics/bd-application-procedures.

pharmacy and pharmacology are found in eighty percent of the NCAs that compiled the questionnaire. Other areas of expertise include expertise in toxicology, microbiology, chemistry and biochemistry. One can postulate that expertise in varying areas are beneficial in an entity regulating medicinal products taking into consideration that varying services are offered by the entity that require different expertise.

Training in the field of veterinary pharmaceutical sciences was identified, in this study, as a requirement but the provision of training differed among different NCAs with suggestions indicating that training was given internally, or externally from conferences and specific courses. In some cases, training was given on the job. In entities where there is no specific expertise available, the workload is not enough to require someone dedicated to a particular task or the workload is too high, additional help may be sought from external experts.

The analysis of the regulatory framework and an insight to the resources other entities regulating veterinary medicines alone or in combination with other areas provides a basis to support the establishment for a support office within an entity specialised in human medicines to extend its services to veterinary medicines. The proposal is based on the data received from the ten NCAs that compiled the questionnaire. It may be that an increased number of responses would have provided a more solid basis or a different idea of how such an office would operate.

A paradigm for the pharmacist education in veterinary sciences is the veterinary-pharmacy bicycle. A bicycle demonstrates how two separate entities, seemingly so different and far apart from each other come together and strive for excellence in the field

of animal health (Figure 4.1). The bicycle has two separate independent wheels that are located far apart from each other. Their only connection to each other is that they are both connected to the frame of the bicycle. The driver (the pharmacist) provides the force to move the pedals which turns the chain. When the two wheels are aligned and the chain is tightened, the bicycle can be driven towards a destination. If the wheels are out of synchrony or the chain is not tightened, the wheels cannot work together, and the bicycle does not perform its function. In this paradigm, regulation and policy are represented by the front wheel and the perception of the pharmacist is represented by the back wheel. Spokes in the bicycle rim add strength to the wheel. Regulations that stimulate innovation, reduce administrative burden, increase the availability of veterinary medicinal products and strengthen the fight against antibiotic resistance create an environment, which is new, modern, and fit for purpose. Regulatory authorities have policies and activities in place to ensure the protection of public and animal health and access to safe and effective medicine. A strong positive perception of the pharmacist's role in animal care will increase the pharmacist's visibility in this regard within the community, which further improves animal care.

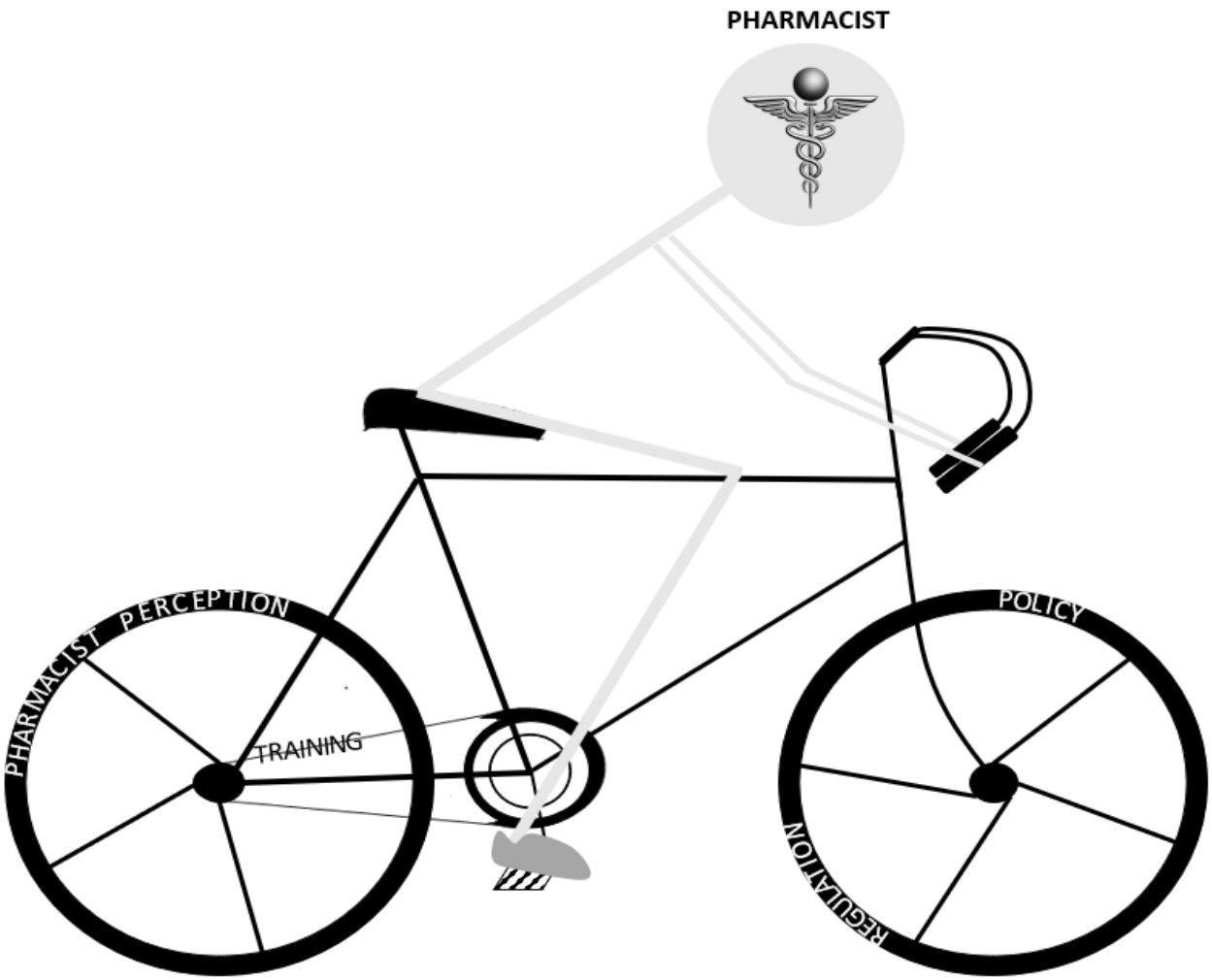

Figure 4.1: The veterinary-pharmacy bicycle: the pharmacist education in veterinary pharmaceutical sciences paradigm

The wheels individually represent the current state of the regulatory framework and the current perception of the pharmacists with respect to animal care. The spokes in the wheel reflect the perceptions of the role of the pharmacist in animal care identified during this study from 'VSP-Q', 'PHP-Q' and 'POP-Q'. The pharmacist is perceived as not adequately skilled to safely dispense medication for use in animals and provide advice for certain chronic conditions that are also seen in humans. Pharmacists are underutilised and should be given training to understand the differences in animal physiology. Collaboration between pharmacists and veterinary surgeons is lacking. The metaphorical front wheel and spokes of the veterinary-pharmacy bicycle represents the regulation and policy that currently govern veterinary medicinal products and their enforcement, the NCAs that regulate veterinary medicinal products and their collaboration with other entities as well as challenges of access to medicine as reported in 'VSP-Q', 'PHP- Q' and 'POP-Q'.

In the proposed paradigm, the driver is the pharmacist and training in veterinary pharmaceutical sciences is represented by the chain. The driver pedalling the bike, moves the chain and in turn moves the bicycle forward. The turning of the wheels represents the evolution of the perception of the pharmacist and the evolution of regulation and policy towards the same goal. The goal at the finish line is a regulatory framework that aims to protect and safeguard animal health in the same ways, and to the same standards, as we do humans and the provision of high quality pharmaceutical care and of safe and effective medicine.

A pharmacist trained in veterinary pharmaceutical sciences has the power to affect change. A trained pharmacist will be skilled to safely dispense medicine for use in

animals and knowledgeable to provide advice in chronic conditions seen in animals. This will strengthen the role of the pharmacist in animal care and increase interdisciplinary collaboration between veterinary surgeons to provide high quality pharmaceutical care and the provision of safe and effective medicine that equals that given to humans. Pharmacists trained in veterinary pharmaceutical sciences may be more heavily involved in aspects concerning the regulation of veterinary medicinal products. In addition, trained pharmacists may also be involved in the assessment of veterinary medicinal products as part of an entity that is specialised in human medicines but is extending its service to veterinary medicinal products. Such an endeavour may increase the participation of that entity both at a local and European level. Trained pharmacists may play a role in improving access to medicines such as compounding medication for use in animals. Pharmacists should be the drivers to enact change in veterinary medicine and animal care, and this is represented by the resulting will of the pharmacist to obtain knowledge in veterinary pharmaceutical sciences.

4.2. Limitations

Some of the findings reported in this study may have been influenced by selection bias. Ideal answers may have been selected by veterinary surgeons and pharmacists instead of what is commonly practiced, and the real scenario may not have been reflected. A better response rate with both veterinary surgeons and pharmacists could have strengthened the results obtained and assured better representativeness. The questionnaires were mostly structured using close-ended questions, introducing a potential for bias since responses available are limited. The use of Likert scales limited the options of choice. Participants who were rushed while filling in the questionnaires could choose a random response and

introduce bias. This study was a cross-sectional study that collected data on one occasion only. The lack of a longitudinal perspective is another limitation.

4.3. Recommendations for Further Study

The training programme for pharmacists, in veterinary pharmaceutical science, which has been validated was an outcome from this research. A recommendation for future work would be a pilot study to assess the feasibility of implementing it as part of an established curriculum or incorporate it as part of a new curriculum focussed on veterinary pharmaceutical sciences.

Exposure to a veterinary clinic setting reveals the uniqueness of prescribing and administering medicines to animal patients (Adrian et al., 2014; Young et al, 2018). Findings from this study showed that placements or rotations within a veterinary clinic setting were suggested as a method by which training in veterinary pharmaceutical sciences may be obtained. A recommendation for further studies would be to evaluate the feasibility of incorporating a placement or rotation within the veterinary sector into established pharmacy curricula.

Results from the study showed that veterinary surgeons, pharmacists and pet owners would like a community pharmacy to offer services such as glucose checks and urine testing for animal patients. Recommendations for future work include assessing the acceptability by pharmacists of incorporating such services within a community pharmacy setting.

This study proposes the basic framework for a support office intended to be implemented within an entity specialised in human medicine to extend its services to veterinary medicine with respect to assessment of veterinary medicines and medicines information. Future work could include evaluating the feasibility of implementing the support office by conducting a pilot study. The study indicated that provision and dissemination of medicines information requires less rigorous training suggesting that medicines information would be a better candidate to use in a pilot study.

The therapeutic potentials seen with the use of cannabinoids for the treatment of pain, inflammation, glaucoma and rheumatoid arthritis, among others, has increased interested to the therapeutic potential of cannabinoids in veterinary medicine (Landa et al., 2016). In 2018, Malta enacted the Production of Cannabis for Medicinal and Research Purposes Act which laid down measures to permit the production of cannabis for medical and research purposes.[40] This required a change in the Drug Dependence Act to amend the regulation concerning the prescribing of cannabis preparations. A recommendation for future study would be to investigate the use of cannabis products in veterinary medicine.

4.4. Conclusion

The traditional mindset of how we view pets is changing. Animals are becoming increasingly important in our lives. Pet owners are viewing their pets as members of the family and this is changing the way in which animals are being cared for (Young et al, 2017; Young et al, 2018). With the advances in medicine, pets are living longer. Longer

[40] Ministry for Justice, Culture and Local Government. Chapter 578 Production of Cannabis for medicinal and research purposes act [Internet] Malta: The Ministry 2018: 1-9 [cited 2020 Jun 23]. Available from: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=12821&l=1.

life expectancies increase the probability of development of chronic diseases in animals (Bennett et al, 2018).

The responsibility to provide high-quality pharmaceutical care for animal patients challenges pharmacist knowledge regarding indications, dosages, and drug administration in animals. This research assessed the perception of the role of the pharmacist in animal care and identified challenges and barriers of access to medicine. The pharmacist is perceived as not able to safely dispense and provide advice for medication use in animals. Pharmacists and veterinary surgeons think that pharmacists should be given training in veterinary pharmaceutical sciences. A training programme in veterinary pharmaceutical sciences was developed and validated. The training programme was intended for pharmacists to increase their knowledge in veterinary pharmaceutical sciences and includes veterinary disease states and pharmacotherapy of the ten most common disease states seen in animals. An additional area includes the regulation of veterinary medicinal products.

An entity that is specialised in the regulation of human medicinal products may extend its services to include veterinary products. The research analysed the regulatory framework for veterinary medicinal products including the requirements for the dossier of medicinal products to identify similarities and differences between veterinary and human medicinal products. The resources of different National Competent Authorities that regulate veterinary medicines with respect to the assessment of veterinary medicinal products and medicines information were identified. Collaboration with other entities was also included. The data obtained was used to draft a proposal for the establishment of a support office within an entity specialised in the regulation of human medicinal

product. The support office would be involved in the assessment of veterinary medicinal products and medicines information. The proposal provides a basic framework for the setup, training and expertise required for such a support office.

The veterinary-pharmacy bicycle was used to represent the trained pharmacist as the driver. The turning of the wheels represents the evolution of the perception of the pharmacist and the evolution of regulation and policy towards the same goal. The goal at the finish line is a regulatory framework that aims to protect and safeguard animal health in the same ways, and to the same standards, as we do humans and the provision of high quality pharmaceutical care and of safe and effective medicines, thus helping to achieve excellence in veterinary services.

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Appendix 1

FREC Approval

Request for Ethics Approval

FACULTY RESEARCH AND SURGERY <research-ethics.ms@um.edu.mt> 18 November 2019 at 10:56
To: Dianne Butler <diannebutler@gmail.com>

Dear Ms Butler,

Thank you for your email.

Document attached is sufficient.

Since your application states you have no self-assessment issues, FREC will keep your application for filing and it will not review your application.

You may proceed with your study.

Any ethical and legal issues including data protection issues are your responsibility and that of the supervisor.

Thank you.

Kind regards,
Christabel Gauci
Administrator II
FREC Secretary

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[Quoted text hidden]

Appendix 2

The evolution of the laws governing the veterinary profession and veterinary medicinal products

Directive/ Regulation	Directive	Date	Status
Council Directive 81/851/EEC	The approximation of the laws of the Member States relating to veterinary medicinal products[41]	1981	Repealed
Council Directive 81/852/EEC	The approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products[6]	1981	
Council Directive 90/677/EEC	Extends the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products[6]	1990	
Council Directive 92/74/EEC	Widens the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products[6]	1992	
Directive 90/167/EEC	Lays down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community[42]	1990	In Force
Directive 2001/82/EC	Community code relating to veterinary medicinal products[2]	2001	
Regulation (EC) No 726/2004	Lays down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[43]	2004	
Regulation (EU) 2019/4	The manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC[44]	2019	To be implemented in 2022
Regulation (EU) 2019/6	Regulation of veterinary medicinal products, repealing Directive 2001/82/EC[45]	2019	

[41] The European Parliament and the Council of Europe. Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products. Official Journal of the European Communities 2001;L311:1-66.

[42] Council of European Union. Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community. Official Journal of the European Communities 1990;L92:42-46.

[43] The European Parliament and the Council of Europe. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Text with EEA relevance). Official Journal of the European Communities 2004;L136:1-33.

[44] The European Parliament and the Council of Europe. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC. Official Journal of the European Communities 2019;L4:1-23.

[45] The European Parliament and the Council of Europe. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC. Official Journal of the European Communities 2019;L4:43-1

Appendix 3

The Content Validity Index (CVI) validation method: I-CVI and Ave-CVI values for the questionnaires for veterinary surgeons, pharmacists and pet-owners

Expert Validation of the Questionnaire for Veterinary Surgeons									
Validation domain: Relevance to research									
	Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Number in agreement	I-CVI
Section A	1	4	5	5	5	5	5	6	1.00
	2	4	5	4	5	5	5	6	1.00
	3	4	5	4	5	0	5	5	0.83
	4	5	5	3	5	5	2	4	0.67
	5	5	5	5	5	5	5	5	0.83
Section B	6	5	5	5	5	5	5	6	1.00
	7	5	5	4	5	5	5	6	1.00
	8	5	5	5	5	5	5	6	1.00
	9	5	5	5	5	5	5	6	1.00
	10	5	5	5	5	5	5	6	1.00
	11	5	5	5	5	5	5	6	1.00
	12	5	3	5	4	5	5	5	0.83
	13	5	5	5	5	5	5	6	1.00
	14	5	5	5	5	5	5	6	1.00
Section C	15	5	3	5	0	5	5	4	0.67
	16	5	5	5	5	5	5	6	1.00
	17	5	5	5	5	5	5	6	1.00
	18	5	5	5	5	5	5	6	1.00
	19	5	5	5	5	5	5	6	1.00
	20	5	5	5	5	5	5	6	1.00
	21	5	5	5	5	5	5	6	1.00
	22	5	5	5	5	5	5	6	1.00
	23	5	5	5	5	5	5	6	1.00
	24	5	5	5	5	5	5	6	1.00
	25	5	5	5	5	5	5	6	1.00
	26	5	5	5	0	2	5	4	0.67
	27	5	5	5	0	5	5	5	0.83
	28	5	5	5	5	5	5	6	1.00
	29	5	5	4	5	5	5	6	1.00
	30	5	5	5	5	5	5	6	1.00
	31	5	5	5	5	5	5	6	1.00
	32	5	5	5	5	5	5	6	1.00
								Ave-CVI	0.95

Expert Validation of the Questionnaire for Veterinary Surgeons									
Validation domain: Clarity of questions and statements									
	Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Number in agreement	I-CVI
Section A	1	5	5	5	5	5	5	6	1.00
	2	5	5	5	5	5	5	6	1.00
	3	5	5	5	5	0	5	5	0.83
	4	5	3	5	5	5	0	4	0.67
	5	5	5	5	5	5	5	6	1.00
Section B	6	5	3	5	5	5	5	5	0.83
	7	5	5	5	5	4	5	6	1.00
	8	5	5	5	5	2	5	5	0.83
	9	5	5	5	5	5	5	6	1.00
	10	5	5	5	5	5	4	6	1.00
	11	5	5	5	5	5	4	6	1.00
	12	5	3	5	3	5	5	4	0.67
	13	5	5	5	3	3	5	4	0.67
	14	5	5	5	4	5	5	6	1.00
Section C	15	5	5	5	0	5	5	5	0.83
	16	5	5	5	5	5	5	6	1.00
	17	5	5	5	5	5	5	6	1.00
	18	5	5	5	3	5	5	5	0.83
	19	5	5	5	5	5	5	6	1.00
	20	5	5	5	5	5	5	6	1.00
	21	5	5	5	5	5	5	6	1.00
	22	5	5	5	5	5	5	6	1.00
	23	5	5	5	5	5	5	6	1.00
	24	5	5	5	5	5	5	6	1.00
	25	5	5	5	5	5	5	6	1.00
	26	5	5	5	0	5	5	5	0.83
	27	5	5	5	0	5	5	5	0.83
	28	5	5	5	5	5	5	6	1.00
	29	5	5	5	5	5	5	6	1.00
	30	5	5	5	5	5	5	6	1.00
	31	5	5	5	5	5	5	6	1.00
	32	5	5	5	5	5	5	6	1.00
								Ave-CVI	0.93

Expert Validation of the Questionnaire for Veterinary Surgeons									
Validation domain: Structure and layout of questionnaire									
	Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Number in agreement	I-CVI
Section A	1	5	5	5	5	5	5	6	1.00
	2	5	5	5	5	5	5	6	1.00
	3	5	5	5	5	0	5	5	0.83
	4	5	5	5	5	5	0	5	0.83
	5	5	5	5	5	5	5	6	1.00
Section B	6	5	5	5	5	5	5	6	1.00
	7	5	5	5	5	5	5	6	1.00
	8	5	5	5	5	5	5	6	1.00
	9	5	3	5	5	5	5	5	0.83
	10	5	5	5	3	5	5	5	0.83
	11	5	5	5	5	5	5	6	1.00
	12	5	4	5	5	5	5	6	1.00
	13	5	5	5	1	5	5	5	0.83
	14	5	5	5	4	5	5	6	1.00
Section C	15	5	5	5	0	5	5	5	0.83
	16	5	5	5	5	5	5	6	1.00
	17	5	5	5	5	5	5	6	1.00
	18	5	5	5	5	5	5	6	1.00
	19	5	5	5	5	5	5	6	1.00
	20	**5**	**5**	**5**	**3**	**2**	**5**	**4**	**0.67**
	21	5	5	5	5	5	5	6	1.00
	22	5	5	5	5	5	5	6	1.00
	23	5	5	5	5	5	5	6	1.00
	24	5	5	5	5	5	5	6	1.00
	25	5	5	5	5	5	5	6	1.00
	26	5	5	5	0	5	5	5	0.83
	27	5	5	5	0	5	5	5	0.83
	28	5	5	5	5	5	5	6	1.00
	29	5	5	5	5	5	5	6	1.00
	30	5	5	5	5	5	5	6	1.00
	31	5	5	5	5	5	5	6	1.00
	32	**5**	**5**	**5**	**2**	**2**	**5**	**4**	**0.67**
								Ave-CVI	**0.94**

Expert Validation of the Questionnaire for Pharmacists									
Validation domain: Relevance to research									
	Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Number in agreement	I-CVI
Section A	1	5	5	5	5	5	5	6	1.00
	2	2	1	5	5	5	5	4	0.67
	3	5	1	2	5	5	5	4	0.67
	4	1	5	5	5	5	5	5	0.83
	5	5	5	5	5	5	5	6	1.00
Section B	6	5	5	5	5	5	5	6	1.00
	7	5	5	5	5	5	5	6	1.00
	8	5	5	5	5	5	5	6	1.00
	9a	5	5	5	5	5	5	6	1.00
	9b	5	5	5	5	5	5	6	1.00
	10	5	5	5	5	5	5	6	1.00
	11a	5	5	5	5	5	5	6	1.00
	11b	5	5	5	5	5	5	6	1.00
Section C	12a	5	5	5	5	5	5	6	1.00
	12b	5	5	5	5	5	5	6	1.00
	13a	5	5	5	5	5	5	6	1.00
	13b	5	5	5	5	5	5	6	1.00
	14	5	5	5	5	5	5	6	1.00
	15	5	5	5	5	5	5	6	1.00
Section D	16	5	5	5	5	5	5	6	1.00
	17	5	5	5	5	5	5	6	1.00
	18	5	5	5	5	5	5	6	1.00
	19	5	5	5	5	5	5	6	1.00
	20	5	5	5	5	5	5	6	1.00
	21	5	5	5	5	5	5	6	1.00
	22	5	5	5	5	5	5	6	1.00
	23	5	5	5	5	5	5	6	1.00
	24	5	5	5	5	5	5	6	1.00
	25	5	5	5	5	5	5	6	1.00
	26	5	5	5	5	5	5	6	1.00
	27	5	5	5	5	5	5	6	1.00
	28	5	5	5	5	5	5	6	1.00
	29	5	5	5	5	5	5	6	1.00
	30	5	5	5	5	5	5	6	1.00
								Ave-CVI	0.98

Expert Validation of the Questionnaire for Pharmacists									
Validation domain: Clarity of questions and statements									
	Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Number in agreement	I-CVI
Section A	1	5	5	5	5	5	5	6	1.00
	2	5	5	5	5	5	5	5	0.83
	3	5	5	5	5	5	5	6	1.00
	4	5	5	5	5	5	5	5	0.83
	5	5	5	5	5	5	5	6	1.00
Section B	6	5	5	5	5	5	5	6	1.00
	7	5	5	5	5	5	5	6	1.00
	8	5	3	5	5	5	5	5	0.83
	9a	5	5	5	5	5	5	6	1.00
	9b	5	5	5	5	5	5	6	1.00
	10	5	5	5	5	5	5	6	1.00
	11a	5	5	5	5	5	5	6	1.00
	11b	5	3	5	5	5	5	5	0.83
Section C	12a	5	5	5	5	5	5	6	1.00
	12b	5	5	5	5	5	5	6	1.00
	13a	5	5	5	5	5	5	6	1.00
	13b	5	5	5	5	5	5	6	1.00
	14	5	5	5	5	5	5	6	1.00
	15	5	5	5	5	5	5	6	1.00
Section D	16	5	5	5	5	5	5	6	1.00
	17	5	5	5	5	5	5	6	1.00
	18	5	5	5	5	5	5	6	1.00
	19	5	5	5	5	5	5	6	1.00
	20	5	5	5	5	5	5	6	1.00
	21	5	5	5	5	5	5	6	1.00
	22	5	5	5	5	5	5	6	1.00
	23	5	5	5	5	5	5	6	1.00
	24	5	5	5	5	5	5	6	1.00
	25	5	5	5	5	5	5	6	1.00
	26	5	5	5	5	5	5	6	1.00
	27	5	5	5	5	5	5	6	1.00
	28	5	5	5	5	5	5	6	1.00
	29	5	5	5	5	5	5	6	1.00
	30	5	3	5	5	5	5	5	0.83
								Ave-CVI	**0.98**

Expert Validation of the Questionnaire for Pharmacists									
Validation domain: Structure and layout of questionnaire									
	Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Number in agreement	I-CVI
Section A	1	5	5	5	5	5	5	6	1.00
	2	5	5	5	5	5	5	6	1.00
	3	5	5	5	5	5	5	6	1.00
	4	5	5	5	5	5	5	6	1.00
	5	5	5	5	5	5	5	6	1.00
Section B	6	5	5	5	5	5	5	6	1.00
	7	5	5	5	5	5	5	6	1.00
	8	4	5	5	5	5	5	6	1.00
	9a	5	5	5	5	5	5	6	1.00
	9b	5	5	5	5	5	5	6	1.00
	10	5	5	5	5	5	5	6	1.00
	11a	5	5	5	5	5	5	6	1.00
	11b	**3**	**5**	**5**	**3**	**5**	**5**	**4**	**0.67**
Section C	12a	5	5	5	5	5	5	6	1.00
	12b	5	5	5	5	5	5	6	1.00
	13a	5	5	5	5	5	5	6	1.00
	13b	5	5	5	5	5	5	6	1.00
	14	5	5	5	5	5	5	6	1.00
	15	5	5	5	5	5	5	6	1.00
Section D	16	5	5	5	5	5	5	6	1.00
	17	5	5	5	5	5	5	6	1.00
	18	5	5	5	5	5	5	6	1.00
	19	5	5	5	5	5	5	6	1.00
	20	5	5	5	5	5	5	6	1.00
	21	5	5	5	5	5	5	6	1.00
	22	5	5	5	5	5	5	6	1.00
	23	5	5	5	5	5	5	6	1.00
	24	5	5	5	5	5	5	6	1.00
	25	5	5	5	5	5	5	6	1.00
	26	5	5	5	5	5	5	6	1.00
	27	5	5	5	5	5	5	6	1.00
	28	5	5	5	5	5	5	6	1.00
	29	5	5	5	5	5	5	6	1.00
	30	5	5	5	5	5	5	6	1.00
								Ave-CVI	**0.99**

Expert Validation of the Questionnaire for Pet Owners									
Validation domain: Relevance to research									
	Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Number in agreement	I-CVI
Section A	1	3	5	5	5	5	5	5	0.83
	2	3	5	5	5	5	4	5	0.83
	3	4	5	5	5	5	5	6	1.00
	4	5	5	5	4	5	5	6	1.00
Section B	5	5	5	5	5	5	5	6	1.00
	6	5	5	5	5	5	5	6	1.00
	7	3	5	5	5	5	5	5	0.83
	8	4	5	5	5	5	5	6	1.00
	9	4	0	5	5	5	5	5	0.83
	10	4	5	5	5	5	5	6	1.00
	11	4	5	5	5	5	5	6	1.00
	12	4	5	5	5	5	5	6	1.00
	13	4	5	4	5	5	5	6	1.00
	14	4	5	5	5	5	5	6	1.00
	15	4	5	5	4	0	5	5	0.83
	16	4	0	5	5	5	5	5	0.83
Section C	17	4	5	5	5	5	5	6	1.00
	18	5	5	5	5	5	5	6	1.00
	19	5	5	5	5	5	5	6	1.00
	20	**5**	**0**	**5**	**2**	**5**	**5**	**4**	**0.67**
	21	5	5	5	5	5	5	6	1.00
	22	5	5	5	5	5	5	6	1.00
	23	5	0	5	5	5	5	5	0.83
	24	5	5	5	4	5	5	6	1.00
	25	4	5	5	5	5	5	6	1.00
	26	5	0	5	5	5	5	5	0.83
	27	5	5	5	5	5	5	6	1.00
	28	5	5	5	5	5	5	6	1.00
	29	5	5	5	5	5	5	6	1.00
								Ave-CVI	**0.94**

Expert Validation of the Questionnaire for Pet Owners									
Validation domain: Clarity of questions and statements									
	Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Number in agreement	I-CVI
Section A	1	5	5	5	5	5	5	6	1.00
	2	5	5	5	4	5	5	6	1.00
	3	5	5	5	5	5	5	6	1.00
	4	5	5	5	4	5	5	6	1.00
Section B	5	5	5	5	5	5	5	6	1.00
	6	5	5	5	4	5	5	6	1.00
	7	5	5	5	2	5	5	5	0.83
	8	5	5	5	2	5	5	5	0.83
	9	5	0	5	5	5	5	5	0.83
	10	5	5	5	5	5	5	6	1.00
	11	5	5	5	5	5	5	6	1.00
	12	5	5	5	5	5	5	6	1.00
	13	5	5	5	5	5	5	6	1.00
	14	5	5	5	5	5	5	6	1.00
	15	5	5	5	0	4	5	5	0.83
	16	**5**	**0**	**3**	**5**	**5**	**5**	**4**	**0.67**
Section C	17	5	5	5	5	5	5	6	1.00
	18	5	5	5	5	5	5	6	1.00
	19	5	5	5	5	5	5	6	1.00
	20	**5**	**0**	**5**	**2**	**4**	**5**	**4**	**0.67**
	21	5	5	5	4	5	5	6	1.00
	22	5	5	5	5	5	5	6	1.00
	23	5	0	5	5	5	5	5	0.83
	24	5	5	5	3	5	5	5	0.83
	25	5	5	5	5	5	5	6	1.00
	26	5	0	5	4	5	5	5	0.83
	27	5	5	5	5	5	5	6	1.00
	28	5	5	5	5	5	5	6	1.00
	29	5	5	5	5	5	5	6	1.00
								Ave-CVI	**0.94**

Expert Validation of the Questionnaire for Pet Owners									
Validation domain: Structure and layout of questionnaire									
	Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Number in agreement	I-CVI
Section A	1	5	5	5	5	5	5	6	1.00
	2	5	5	5	4	5	5	6	1.00
	3	5	5	5	5	5	5	6	1.00
	4	5	5	5	5	5	5	6	1.00
Section B	5	5	5	5	5	5	5	6	1.00
	6	5	5	5	4	3	5	6	1.00
	7	5	5	4	5	3	5	5	0.83
	8	5	3	5	2	4	5	4	0.67
	9	5	0	5	5	4	5	5	0.83
	10	5	5	5	5	5	5	6	1.00
	11	5	3	5	5	5	5	5	0.83
	12	5	5	5	5	5	5	6	1.00
	13	5	5	5	5	5	5	6	1.00
	14	5	5	5	5	5	5	6	1.00
	15	5	5	5	4	0	5	5	0.83
	16	5	0	3	5	5	5	4	0.67
Section C	17	5	5	5	5	5	5	6	1.00
	18	5	5	5	5	5	5	6	1.00
	19	5	5	5	5	5	5	6	1.00
	20	5	0	5	5	5	5	5	0.83
	21	5	5	5	5	5	5	6	1.00
	22	5	5	5	5	5	5	6	1.00
	23	5	0	5	5	5	5	5	0.83
	24	5	5	5	5	5	5	6	1.00
	25	5	5	5	5	5	5	6	1.00
	26	5	0	5	5	5	5	5	0.83
	27	5	5	5	5	5	5	6	1.00
	28	5	5	5	5	5	5	6	1.00
	29	5	2	3	5	5	5	4	0.67
								Ave-CVI	0.93

Appendix 4

Questionnaire items revised or omitted from the VSP-Q, PHP-Q and POP-Q

The veterinary surgeon's perception of the role of the pharmacist, challenges and barriers regarding access to medicinal products and animal care.

Question or statement number	Modification/Omission
4	Omission: It was suggested to remove the question as it is implied that level of education is tertiary.
12, 15	Omission: Questions were deemed to be very similar so question 12 was omitted. Modification: The relevant options from question 12 were integrated with question 15.
13	Modification: Extensive modification to clarify time periods used. The scale from 'very often' to 'never' was modified to a scale ranging from 'daily' to 'never'.
20	Omission: Question was deemed to be similar to question 21 so was omitted.
26	Omission: It was decided that the question was not very relevant so was removed.
32	Modification: Question was extensively modified to give options rather than leave it open-ended to increase chances of respondents answering the question.

Question or statement number	Comments
2	Addition: Recommended to add the 'Locality of Practice' to Section A.
6	Modification: Modified to improve clarity of the question; It was suggested to add a rating scale to each of the challenges.
7	Addition: It was suggested to include the types of surgical procedure that are performed.
9	Addition: Recommended to add a question to identify who performs compounding where the service is offered. Modification: include a definition of compounding at the start of the questionnaire.
10	Modification: modify the question so that it is answered only if the answer to the previous question was 'Yes'.

11	Modification: It was suggested to add a rating scale to each of the challenges.
12	Modification: Modified to improve clarity of the question; It was suggested to add a rating scale to each of the challenges.
14	Modification: To add 'Others' to the list of options.
18	Modification: statement was reworded to remove negatives to avoid confusion.
28	Addition: It was suggested to add a question to ask how pharmacists can increase their knowledge and include options to complement question 28.

The perception of the role of the pharmacist, challenges and barriers regarding access to medicinal products and animal care

Question or statement number	**Modification/Omission**
2	Omission: This question was determined to not be relevant to the scope of the questionnaire
3	Omission: It was suggested to remove the question as it is implied that level of education is tertiary.
11b	Modification: Modified extensively to include list of options rather than having an open-ended question

Question or statement number	Other Comments
8	Modification: re-worded to improve clarity and understanding.
30	Modification: Removal of 'In your opinion'

The pet owner's perception of the role of the pharmacist, challenges and barriers regarding access to medicinal products and animal care.

Question or statement number	Modification/Omission
8	Modification: the question was extensively modified and split into 2 separate questions.
16	Modification: Extensive modification to clarify time periods used. The scale from 'very often' to 'never' was modified to a scale ranging from 'daily' to 'never'.
20	Omission: Question 20 was removed due to its similarity to question 18.
29	Modification: Question was extensively modified to give options rather than leave it open-ended to increase chances of respondents answering the question.

Question or statement number	Comments
9	Modification: It was recommended to reduce the time frame for 5 years to 6 months.
10	Modification: It was suggested to add definitions for Community Pharmacy and Community Pharmacist. Modification: It was suggested to add 'on-line as one of the options for purchasing medicine.
11	Modification: It was suggested to slightly modify the wording to improve clarity.
17	Modification: It was suggested to remove the word 'knowledgeable' since knowledge of pharmacists was addressed in a previous question,
21	Modification: It was suggested to reword the statement to improve its clarity.
23	Modification: It was suggested to move the question after question 18 to improve the structure of the questionnaire.
26	Modification: Another option was added to include those owners who already ask the pharmacist for advice.

Appendix 5

Questionnaires for veterinary surgeons (VSP-Q), pharmacists (PHP-Q) and pet-owners (POP-Q)

The veterinary surgeon's perception of the role of the pharmacist, challenges and barriers regarding access to medicinal products and animal care

For the purpose of this questionnaire the community pharmacist is a healthcare professional who is responsible for the provision of pharmaceutical services to the public and provides personalised advice about health and medicines. The hospital is the acute general hospital offering services to the general public.

Section A - Demographic data

1	Gender	☐ Male ☐ Female ☐ Other	**2**	Locality of residence
3	Age	☐ 18 – 29 ☐ 30 – 39 ☐ 40 – 49 ☐ 50 – 59 ☐ 60 – 69 ☐ 70 +	**4**	Locality of practice

Section B – Challenges of access to medicine

Please answer the questions below to the best of your knowledge

5	How long have you been practicing as a vet?	_____ years
6	What percentage of your patients fall under the categories mentioned? Please provide an estimate for each of the categories.	Small animals: _____ Large animals: _____ Exotic animals: _____ Avian species: _____ Others: _____
7	Do you dispense medication against another veterinary surgeon's prescription?	☐ Yes ☐ No ☐ Not anymore ☐ No, but I am considering adding this
8a	Do you perform surgical procedures?	☐ Yes ☐ No ☐ Not anymore ☐ No, but I am considering adding this
8b	If you perform surgical procedures, which procedures do you perform?	☐ Soft tissue surgery ☐ Orthopaedic surgery ☐ Ophthalmic surgery ☐ Dental procedures ☐ Other: _____
9a	Do you perform compounding i.e. modifying the formulation available to make it tailored for the patient?	☐ Yes ☐ No ☐ Not anymore ☐ No, but I am considering adding this

9b	If you compound, which of the following services do you offer?	☐ Medication flavouring ☐ Individualised medication strength/dose ☐ Individualised dosage forms ☐ Combination medications ☐ Others: _____
9c	If you offer compounding, who performs the compounding of medicines?	☐ Veterinary surgeon ☐ Veterinary nurse ☐ Veterinary technician ☐ Student interns ☐ Pharmacist ☐ Other _____
10	What are the challenges pet owners face when giving medications to their pets? Tick all that apply and rate from 1 to 5 (1 – least challenging, 5 – most challenging) where applicable.	☐ Injured by pet whilst trying to give medications _____ ☐ Pet would not eat/swallow medication _____ ☐ Medication dosing/administration was difficult or messy _____ ☐ Medication smelled bad to owner _____ ☐ Compliance to treatment regimen _____ ☐ Other: _____
11	What are the challenges you face when deciding on treatment options for your patients? Tick all that apply and rate from 1 to 5 (1 – least challenging, 5 – most challenging).	☐ Dosage form not appropriate for animal administration _____ ☐ Dose too large for animals _____ ☐ Owners not able to administer the available formulation _____ ☐ Medicine not available in the community _____ ☐ No access to medicinal products that are only available from hospital _____
12	How often do you prescribe human medicines for use in animals?	☐ Daily ☐ Weekly ☐ Monthly ☐ Yearly ☐ Never
13	What are the main motivations behind prescribing human medicines for use in animals?	☐ The Veterinary medicinal product required is not available ☐ Veterinary equivalents do not exist ☐ Problem for pet owner to access clinic or pharmacy ☐ I do not prescribe human medicine for use in animals ☐ Other: _____

Section C – Perception of the pharmacist and pharmacy services.

For questions 15 – 20 and 22 - 29, please mark the degree with which you agree with the statements. Tick all that apply for question 21 and 30.

		Strongly Disagree	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
14	Veterinary surgeons are increasingly prescribing human medications for use in animals.	☐	☐	☐	☐	☐

15	Community pharmacists possess competence in caring for veterinary patients.	☐	☐	☐	☐	☐
16	Community pharmacists are prepared to safely dispense and provide advice for animal prescriptions.	☐	☐	☐	☐	☐
17	Community pharmacists are able to give advice for certain chronic conditions, seen in humans, that are also seen in animals.	☐	☐	☐	☐	☐
18	Community pharmacists have the knowledge and expertise to compound medications for pets.	☐	☐	☐	☐	☐
19	Community pharmacists should be given training to understand the differences in animal physiology and provide appropriate drug information to support pet owners and serve as inter-professional collaborators with veterinary surgeons.	☐	☐	☐	☐	☐
20	How can pharmacists increase their knowledge in veterinary therapeutics?	☐ Include credits and/or modules in curricula ☐ Design training programmes in the form of short courses ☐ Allow students to have placements in veterinary clinics ☐ Other _____				
		Strongly Disagree	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
21	There is the need for pharmacists and veterinary surgeons to collaborate to provide the best care for animal patients.	☐	☐	☐	☐	☐
22	Pharmacists are able to help veterinary surgeons navigate the wealth of information on drug products to assist them in making appropriate drug choices.	☐	☐	☐	☐	☐
23	Pharmacists are underutilised and not involved in veterinary therapeutics.	☐	☐	☐	☐	☐
24	I would consider collaborating with a community pharmacist to increase the animals' access to medicine that is safe and effective.	☐	☐	☐	☐	☐
25	I would consider collaborating with a community pharmacist to provide compounded medication to my patients.	☐	☐	☐	☐	☐

26	I am concerned that collaborating with a community pharmacist to provide compounded medications to my patients would result in a loss of revenue for my practice.	☐	☐	☐	☐	☐
27	I am concerned that collaborating with a community pharmacist to provide compounded medications to my patients would result in a communication barrier between my patients' owners and myself.	☐	☐	☐	☐	☐
28	Enhancing veterinary-pharmacy interprofessional education can benefit both professions.	☐	☐	☐	☐	☐

29	Are there any other services that you would like to be offered by community pharmacies/pharmacists?	☐ Offer a service of compounding for animals ☐ Glucose checks for animals ☐ Urine tests for animals (using test strips) ☐ Pharmacy to stock veterinary medicinal products ☐ Veterinary medicinal products to be handled and treated at the same standards as human medicinal products ☐ Other _____

The Perception of the Role of the Pharmacist, Challenges and Barriers regarding Access to Medicinal Products and Animal Care

This questionnaire is intended for all pharmacists in all sectors. For the purpose of this questionnaire the community pharmacist is a healthcare professional who is responsible for the provision of pharmaceutical services to the public and provides personalised advice about health and medicines. The hospital is the acute general hospital offering services to the general public.

Section A: Demographic Data

1	Gender	☐ Male ☐ Female ☐ Other	**2**	Age	☐ 18 – 29 ☐ 30 – 39 ☐ 40 – 49 ☐ 50 – 59 ☐ 60 – 69 ☐ 70 +
3	Which sectors do you work in? (within the past 5 years) Tick all that apply.	☐ Community ☐ Hospital ☐ Industry ☐ Regulatory ☐ Academia ☐ Other _____			

Section B: Current Practices
Please answer questions 4-9 if you work / have ever worked as a pharmacist within the community.

4	How long have you been practicing as a pharmacist within the community?	_____ years
5	Locality of practice	
6	How often did/do you dispense medication, for use in animals, against a prescription from a veterinary surgeon?	☐ Daily ☐ Weekly ☐ Monthly ☐ Yearly ☐ Never
7a	Did/Do you perform compounding for medicinal products against a veterinary surgeon's prescription?	☐ Yes (go to 8b) ☐ No
7b	Which of the following did/do you perform?	☐ Medication flavouring ☐ Individualised medication strength/dose ☐ Individualised dosage forms ☐ Combination medications ☐ Others: _____
8	How often did/do pet owners ask you for advice about their pet/s?	☐ Daily ☐ Weekly ☐ Monthly ☐ Yearly ☐ Never

9a	Have you ever had to look up information regarding animals, certain conditions animals suffer from, medication use in animals, administration of medicines to animals to be able to give advice to pet owners?	☐ Yes (go to Q10b) ☐ No ☐ Do not know
9b	Which resources did you refer to?	☐ BSAVA Small Animal formulary ☐ MSD Veterinary Manual ☐ Journal articles ☐ Online search ☐ Other: _____

Section C: Challenges of Access to Medicine

10a	Are you aware of the challenges pet owners face when giving medications to their pets?	☐ Yes (go to Q11b) ☐ No ☐ Do not know

10b What are the perceived challenges pet owners face when giving medications to their pets? Tick all that apply and rate from 1 to 5 (1 – least challenging, 5 – most challenging) where applicable.

	1	2	3	4	5
Injured by pet whilst trying to give medications					
Pet would not eat/swallow medication					
Medication dosing/administration was difficult or messy					
Medication smelled bad to owner					
Compliance to treatment regimen					

11a	Are you aware of the challenges veterinary surgeons face when deciding on treatment options for their patients?	☐ Yes (go to Q12b) ☐ No ☐ Do not know

11b If yes, what are the challenges veterinary surgeons face when deciding on treatment options for their patients? Tick all that apply and rate from 1 to 5 (1 – least challenging, 5 – most challenging).

	1	2	3	4	5
Dosage form not appropriate for animal administration					
Dose too large for animals					
Owners not able to administer the available formulation					
Medicine not available in the community					
No access to medicinal products that are only available from hospital					

12	How often did/do you dispense human medicines for use in animals?	☐ Daily ☐ Weekly ☐ Monthly ☐ Yearly ☐ Never ☐ Not aware that the prescription would be for animals

13	What are the main motivations behind veterinary surgeons prescribing human medicines for use in animals?	☐ The Veterinary medicinal product required is not available ☐ Veterinary equivalents do not exist ☐ Problem for pet owner to access veterinary clinic or veterinary pharmacy ☐ Human medicine for use in animals is not prescribed ☐ Do not know ☐ Other: _____

Section D: Perception of the pharmacist and pharmacy services.

For questions 14 – 26 please mark the degree with which you agree with the statements.
Tick all that apply for questions 27 and 28.

		Strongly Disagree	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
14	Veterinary surgeons are increasingly prescribing human medications for use in animals.	☐	☐	☐	☐	☐
15	Community pharmacists possess competence in caring for veterinary patients.	☐	☐	☐	☐	☐
16	Community pharmacists are prepared to safely dispense and provide advice for animal prescriptions.	☐	☐	☐	☐	☐
17	Community pharmacists are able to give advice for certain chronic conditions, seen in humans, that are also seen in animals.	☐	☐	☐	☐	☐
18	Community pharmacists have the knowledge and expertise to compound medications for pets.	☐	☐	☐	☐	☐
19	Community pharmacists should be given training to understand the differences in animal physiology and provide appropriate drug information to support pet owners and serve as inter-professional collaborators with veterinary surgeons.	☐	☐	☐	☐	☐
20	There is the need for pharmacists and veterinary surgeons to collaborate to provide the best care for animal patients.	☐	☐	☐	☐	☐
21	Pharmacists are able to help veterinary surgeons navigate the wealth of information on drug products to assist them in making appropriate drug choices.	☐	☐	☐	☐	☐

22	Pharmacists are underutilised and not involved in veterinary therapeutics.	☐	☐	☐	☐	☐
23	Collaboration between community pharmacists and veterinary surgeons increases animals' access to medicine that is safe and effective.	☐	☐	☐	☐	☐
24	Pharmacists should collaborate with veterinary surgeons to provide compounded medication to animal patients.	☐	☐	☐	☐	☐
25	Community pharmacists involved in veterinary therapeutics may be perceived as direct competitors by veterinary surgeons.	☐	☐	☐	☐	☐
26	Enhancing veterinary-pharmacy interprofessional education can benefit both professions.	☐	☐	☐	☐	☐

27	How can pharmacists increase their knowledge in veterinary therapeutics? Tick all that apply.	☐ Include study units and/or modules in curricula ☐ Design training programmes in the form of short courses ☐ Allow students to have placements in veterinary clinics ☐ Other _____
28	What other services can be offered by a community pharmacy?	☐ Offer a service of compounding for animals ☐ Glucose checks for animals ☐ Urine tests for animals (using test strips) ☐ Pharmacy to stock veterinary medicinal products ☐ Veterinary medicinal products to be handled and treated at the same standards as human medicinal products ☐ Other _____

The pet owner's perception of the role of the pharmacist, challenges and barriers regarding access to medicinal products and animal care

For the purpose of this questionnaire the community pharmacist is a healthcare professional who is responsible for the provision of pharmaceutical services to the public and provides personalised advice about health and medicines. The community pharmacy is the pharmacy where the community pharmacist is on duty. Compounding medicines is when the formulation of the medicinal product available is modified (flavour changed, one dose is split into smaller doses, tablet/capsule made into liquid form etc.) to make it more tailored for the patient.

Section A – Demographic Data

1	Gender	□ Male □ Female □ Other	2	Locality of residence	
3	Age	□ 18 – 29 □ 30 – 39 □ 40 – 49 □ 50 – 59 □ 60 – 69 □ 70 +	4	Level of Education	□ Primary □ Secondary □ Post-secondary □ Tertiary □ Other _____

Section B – Challenges of access to medicine

5 How many pets do you currently have?

a. 0 b. 1 c. 2 d. 3 e. 4 f. 5+

Please answer Questions 6 – 16 for a pet you have owned in the past 6 months. If you have owned more than one pet, choose the pet with the most prescription medicines for the remainder of this questionnaire.

6	What type of pet do you have?	□ Dog □ Cat □ Bird □ Reptile □ Rodent □ Horse □ Other _____
7	How old is your pet?	
8a	Does your pet have any health problems	□ Yes □ No
8b	If yes, what health problems does your pet have? Tick all that apply.	□ Diabetes □ Low thyroid □ High thyroid □ Arthritis □ Heart Disease □ Other: _____

9	Has your pet been prescribed any medicines in the past 6 months?	□ Yes □ No □ Not sure
10	Where did/do you purchase these medicines from? Tick all that apply.	□ Veterinary Clinic □ Veterinary Pharmacy □ Community Pharmacy □ Online □ Other: _____
11	Has your pet ever been prescribed a medicine that needed to be purchased from a community pharmacy?	□ Yes □ No □ Not sure
12	Has your pet ever been prescribed a medicine that needed to be compounded?	□ Yes □ No □ Not sure
13	What dosage form(s) are your pet's medicines? Tick all that apply.	□ Tablets □ Capsules □ Chews/Treats □ Oral liquid medicine (solution/suspension) □ Ear drops □ Eye drops □ Cream/Ointment □ Injections □ Other: _____
14	How difficult was/is it to give medicines to your pet?	□ Extremely difficult □ Difficult □ Neutral □ Easy □ Extremely easy
15	What are the biggest problems you face when trying to give medicine to your pet? Tick all that apply	□ Injured by pet whilst trying to give medicines □ Pet would not eat/swallow medicine □ Pet becomes very stressed □ Medicine was difficult or messy to give □ Medicine smelled bad to you □ Other: _____
16	How often did/do you go to a community pharmacy and ask the pharmacist for advice about your pet?	□ Always □ Frequently □ Sometimes □ Rarely □ Never

Section C – Perception of the pharmacist and pharmacy services
For questions 17 – 26, please mark the degree with which you agree with the following statements. For question 27 tick one and for question 28 tick all that apply.

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
17	Community pharmacists are skilled in caring for companion animals	□	□	□	□	□
18	Community pharmacists have the knowledge to give advice (administration, mode of action, side-effects etc) regarding human medicine use in animals.	□	□	□	□	□
19	Community pharmacists have the knowledge and skills to compound medicines for my pets.	□	□	□	□	□
20	Community pharmacists can give advice on the common chronic medical conditions that affect our pets.	□	□	□	□	□
21	I prefer to ask my veterinarian for advice regarding my pet's medication, medicinal products and chronic conditions that are also seen in humans than the community pharmacist.	□	□	□	□	□
22	My pet would benefit from having medicines compounded by a community pharmacist.	□	□	□	□	□
23	I would be willing to go out of my way to collect compounded medicine for my pet.	□	□	□	□	□
24	I would be willing to pay over and above the selling price of the prescription drug itself to have a medicine specifically compounded for my pet	□	□	□	□	□
25	I would be more willing to go to a community pharmacist for advice regarding my pet if I can be sure they have the knowledge and skills.	□	□	□	□	□
26	Veterinary surgeons and pharmacists should collaborate to provide the best care for our pets.	□	□	□	□	□

27	I would like to be able to ask the community pharmacist for advice on conditions my pet suffers from.	□ Yes □ No □ Not sure □ I already ask the community pharmacist for advice
28	Are there any other services that you would like to be offered by community pharmacies/pharmacists? Tick all that apply.	□ Offer a service of compounding for animals □ Glucose checks for animals □ Urine tests for animals (using test strips) □ Pharmacy to stock veterinary medicinal products □ Other _____

Il-perċezzjoni tas-sid tal-annimali domestiċi (pets) dwar ir-rwol tal-ispiżjar, l-isfidi u l-ostakli rigward l-aċċess għal prodotti mediċinali u l-kura tal-annimali

Għall-iskop ta' dan il-kwestjonarju spiżjar tal-komunità huwa professjonist fil-qasam tal-kura tas-saħħa li huwa responsabbli għall-provvista ta' servizzi farmaċewtiċi lill-pubbliku u jipprovdi pariri personalizzati dwar is-saħħa u l-mediċini. L-ispiżerija tal-komunità hija l-ispiżerija fejn l-ispiżjar tal-komunità jkun xogħol. Il-Compounding tal-mediċini huwa meta l-formulazzjoni tal-prodott mediċinali disponibbli tiġi modifikata (it-togħma tinbidel, doża waħda tinqasam f'dożi iżgħar, pillola/kapsula magħmula f'forma likwida eċċ.) biex tagħmilha aktar adattata għall-pazjent.

Taqsima A - Dejta Demografika

1	Sess tal-persuna	□ Raġel □ Mara □ Ieħor	2	Lokalità tar-residenza	
3	Età	□ 18 - 29 □ 30 - 39 □ 40 - 49 □ 50 - 59 □ 60 - 69 □ 70 +	4	Livell ta' Edukazzjoni	□ Primarju □ Sekondarju □ Post-sekondarju □ Terzjarju □ Ieħor _____

Taqsima B - L-Isfidi tal-aċċess għall-mediċina

5 Kemm għandek pets (annimali domestiċi) bħalissa?

a. 0 b. 1 c. 2 d. 3 e. 4 f. 5+

Jekk jogħġbok wieġeb l-Mistoqsijiet 6 - 16 għal pet li ilu għandek għal dawn l-aħħar 6 xhur. Jekk għandek iktar minn pet wieħed, agħżel il-pet li għandu l-aktar mediċini bir-riċetta għall-bqija ta' dan il-kwestjonarju.

6	X'tip ta' annimal domestiku għandek?	□ Kelb □ Qattus □ Għasfur □ Rettilu □ Żiemel □ Ieħor _____
7	Kemm għandu żmien il-pet tiegħek?	
8a	Il-pet tiegħek għandu xi problemi tas-saħħa	□ Iva □ Le □ Mhux ċert/a
8b	Jekk iva, liema problemi ta' saħħa għandu l-pet tiegħek? Immarka dawk kollu li japplikaw.	□ Dijabete □ Tirojde (thyroid) baxxa □ Tirojde (thyroid) għolja □ Artrite □ Mard tal-Qalb □ Ieħor _____

9	Il-pet tiegħek ġie preskritt xi mediċini fl-aħħar 6 xhur?	□ Iva □ Le □ Mhux ċert/a
10	Minn fejn xtrajt/tixtri dawn il-mediċini? Immarka dawk kollu li japplikaw.	□ Klinika Veterinarja □ Spiżerija Veterinarja □ Spiżerija tal-Komunità □ Onlajn □ Ieħor: _____
11	Il-pet tiegħek qatt ġie preskritt mediċina li kellha tinxtara minn spiżerija tal-komunità?	□ Iva □ Le □ Mhux ċert/a
12	Il-pet tiegħek qatt ġie preskritt mediċina li kellha bżonn tiġi 'compounded'?	□ Iva □ Le □ Mhux ċert/a
13	Il-mediċini tal-pet tiegħek liema forma (forom) ta' dożaġġ għandhom? Immarka dawk kollu li japplikaw.	□ Pilloli □ Kapsuli □ Chews/Treats □ Mediċina likwida orali (soluzzjoni/sospensjoni) □ Taqtir għall-widnejn □ Taqtir għall-għajnejn □ Krema/Ingwent □ Injezzjonijiet □ Ieħor: _____
14	Kemm kienet/hija diffiċli tagħti l-mediċini lill-pet tiegħek?	□ Estremament diffiċli □ Diffiċli □ Newtrali □ Faċli □ Estremament faċli
15	X'inhuma l-akbar problemi li tiffaċċja meta tipprova tagħti mediċina lill-pet tiegħek? Immarka dawk kollu li japplikaw	□ Iweġġagħni l-pet waqt li tkun qed nipprova nagħti l-mediċini □ Il-pet ma riedx jiekol/jibla' l-mediċina □ Il-pet jiġi stressjat ħafna □ Il-mediċina kienet diffiċli jew iddellek/iċċaflas biex tagħtiha □ Il-mediċina kellha riħa ħażina □ Ieħor: _____
16	Kemm-il darba mort/tmur għand spiżerija komunitarja u tistaqsi lill-ispiżjar għal parir dwar il-pet tiegħek?	□ Dejjem □ Spiss □ Kultant □ Rari □ Qatt

Taqsima Ċ - Perċezzjoni tas-servizzi tal-ispiżjar u tal-ispiżerija
Għall-mistoqsijiet 17 - 26, jekk jogħġbok immarka l-grad li bih taqbel mad-dikjarazzjonijiet li ġejjin. Għall-mistoqsija 27 immarka waħda u għall-mistoqsija 28 immarka dawk kollha li japplikaw.

		Ma Naqbilx Ħafna	Ma Naqbilx	Newtrali	Naqbel	Naqbel Ħafna
17	L-ispiżjara tal-komunità huma mħarrġa fil-kura għall-annimali kumpannji	□	□	□	□	□
18	L-ispiżjara tal-komunità għandhom l-għarfien li jagħtu pariri (amministrazzjoni, mod ta' azzjoni, effetti sekondarji, eċċ.) rigward l-użu tal-mediċina umana fl-annimali.	□	□	□	□	□
19	L-ispiżjara tal-Komunità għandhom l-għarfien u l-ħiliet biex iħalltu (compound) mediċini għall-pets tiegħi.	□	□	□	□	□
20	L-ispiżjara tal-komunità jistgħu jagħtu pariri dwar il-kundizzjonijiet mediċi kroniċi komuni li jaffettwaw l-pets tagħna.	□	□	□	□	□
21	Nippreferi nistaqsi lill-veterinarju tiegħi għal parir rigward il-mediċini, prodotti mediċinali u kundizzjonijiet kroniċi tal-pet tiegħi li huma wkoll preżenti fil-bnedmin milli lill-ispiżjar tal-komunità.	□	□	□	□	□
22	Il-pet tiegħi jibbenefika minn li jkollu mediċini mħalltin (compounded) minn spiżjar tal-komunità.	□	□	□	□	□
23	Inkun lest li nmur lil hinn minn triqti biex niġbor mediċina mħallta (compounded) għall-pet tiegħi.	□	□	□	□	□
24	Inkun lest li nħallas aktar mill-prezz tal-bejgħ normali tal-mediċina bir-riċetta nnifisha biex ikolli mediċina speċifikament imħallta (compounded) għall-pet tiegħi	□	□	□	□	□
25	Inkun iktar lest li mmur għand spiżjar tal-komunità għal pariri rigward l-pet tiegħi jekk nista' nkun ċert li għandu l-għarfien u l-ħiliet.	□	□	□	□	□
26	Kirurgi u spiżjara veterinarji għandhom jikkollaboraw biex jipprovdu l-aħjar kura għall-pets tagħna.	□	□	□	□	□

27	Nixtieq inkun nista' nistaqsi lill-ispiżjar tal-komunità għal parir dwar il-kundizzjonijiet li jbati minnha l-pet tiegħi.	□ Iva □ Le □ Mhux ċert/a □ Diġà nitlob parir mingħand l-ispiżjar komunitarju
28	Hemm xi servizzi oħra li tixtieq li jkunu offruti mill-ispiżeriji/spiżjara tal-komunità? Immarka dawk kollu li japplikaw.	□ Joffru servizz ta' taħlit (compounding) għall-annimali □ Kontrolli tal-glukożju għall-annimali □ Testijiet tal-awrina għall-annimali (bl-użu ta' strippi tat-test) □ L-ispiżerija tistokkja prodotti mediċinali veterinarji □ Oħrajn _____

Appendix 6

Results for Delphi Round I

Delphi Round 1												
Training programme for pharmacists in veterinary pharmaceutical sciences (Veterinary Disease States)												
	Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Expert 7	Expert 8	Number in agreement	Consensus	% Consensus
Veterinary Disease States (Aims)	1	5	5	5	5	4	5	5	5	8	1.00	100
	2	5	5	5	4	4	5	5	5	8	1.00	100
	3	5	5	5	4	4	5	4	5	8	1.00	100
	4	5	5	5	5	4	5	4	5	8	1.00	100
Veterinary Disease States (Knowledge and Understanding)	5	5	5	5	5	4	5	4	5	8	1.00	100
	6	5	5	5	4	3	5	5	5	7	0.88	88
	7	5	5	5	4	4	5	5	5	8	1.00	100
	8	5	5	5	5	4	5	5	5	8	1.00	100
	9	5	5	5	4	3	5	5	5	7	0.88	88
	10	5	4	5	2	4	5	4	5	7	0.88	88
	11	5	5	5	5	5	5	5	5	8	1.00	100
	12	5	5	5	4	3	5	5	4	7	0.88	88
	13	5	5	5	3	4	5	5	5	7	0.88	88
	14	5	5	5	3	4	5	5	4	7	0.88	88
	15	5	5	5	2	3	5	5	5	6	0.75	75
	16	5	5	5	3	4	5	5	5	7	0.88	88
	17	5	5	5	2	3	5	5	5	6	0.75	75
	18	5	5	5	3	4	5	5	5	7	0.88	88
	19	5	5	5	3	3	5	5	5	6	0.75	75
	20	5	5	5	3	4	5	5	5	7	0.88	88
	21	5	5	5	4	4	5	5	4	8	1.00	100
	22	5	5	5	3	3	5	5	5	6	0.75	75
	23	5	5	5	3	3	5	5	5	6	0.75	75
	24	5	5	5	2	4	5	5	5	7	0.88	88
	25	5	5	5	4	3	5	5	4	7	0.88	88
	26	5	5	5	3	3	5	5	5	6	0.75	75
	27	5	5	5	4	4	5	5	5	8	1.00	100
	28	5	5	5	4	4	5	5	5	8	1.00	100
	29	5	5	5	4	3	5	5	5	7	0.88	88
	30	5	5	5	4	4	5	5	4	8	1.00	100
	31	5	5	5	4	4	5	4	5	8	1.00	100
	32	5	5	5	4	4	5	5	5	8	1.00	100
	33	5	5	5	4	4	5	5	5	8	1.00	100
	34	5	5	5	3	5	5	4	5	7	0.88	88
Veterinary Disease States (Skills)	35	5	5	5	4	5	5	5	5	8	1.00	100
	36	5	5	5	4	3	5	4	5	7	0.88	88
	37	5	5	5	3	4	5	5	5	7	0.88	88
	38	5	5	5	3	4	5	4	5	7	0.88	88
	39	5	5	5	3	4	5	5	4	7	0.88	88
	40	5	5	5	4	4	5	5	5	8	1.00	100
	41	5	5	5	3	4	5	5	5	7	0.88	88
	42	5	5	5	4	4	5	3	5	7	0.88	88
	43	5	5	5	4	4	5	5	5	8	1.00	100
	44	5	5	5	3	4	5	5	4	7	0.88	88
	45	5	5	5	4	4	5	5	5	8	1.00	100
	46	5	5	5	4	4	4	5	4	8	1.00	100

Delphi Round 1											
Training programme for pharmacists in veterinary pharmaceutical sciences (Veterinary Pharmacotherapy)											
	Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Expert 7	Expert 8	Number in agreement	Consensus	% Consensus
Veterinary Pharmacotherapy (Aims)	47	5	5	5	4	5	5	5	5	8	1.00	100
	48	5	5	5	4	4	5	5	5	8	1.00	100
	49	5	5	5	5	5	5	5	4	8	1.00	100
	50	5	5	5	5	5	5	5	4	8	1.00	100
	51	**5**	**5**	**3**	**4**	**4**	**5**	**3**	**5**	**6**	**0.75**	**75**
	52	5	5	5	4	5	5	5	5	8	1.00	100
	53	5	5	5	4	5	5	5	5	8	1.00	100
	54	5	5	5	4	5	5	5	5	8	1.00	100
	55	5	5	5	4	4	5	5	4	8	1.00	100
Veterinary Pharmacotherapy (Knowledge and Understanding)	56	5	5	5	5	4	5	5	4	8	1.00	100
	57	5	5	5	5	5	5	5	4	8	1.00	100
	58	5	5	5	4	4	5	4	5	8	1.00	100
	59	5	5	5	3	4	5	5	4	7	0.88	88
	60	5	5	5	4	5	5	5	4	8	1.00	100
	61	5	5	5	4	4	5	5	4	8	1.00	100
	62	5	5	5	4	4	5	5	5	8	1.00	100
	63	5	5	5	3	4	5	5	5	7	0.88	88
	64	5	5	5	4	4	5	5	5	8	1.00	100
	65	5	5	5	4	4	5	5	5	8	1.00	100
	66	5	5	5	4	4	5	5	5	8	1.00	100
	67	5	5	5	3	4	5	5	5	7	0.88	88
	68	5	5	5	4	4	5	5	5	8	1.00	100
	69	5	5	5	4	4	5	5	5	8	1.00	100
	70	5	5	5	4	4	5	5	4	8	1.00	100
	71	5	5	5	5	4	5	5	5	8	1.00	100
	72	5	5	5	3	4	5	5	4	7	0.88	88
	73	5	5	5	3	4	5	5	5	7	0.88	88
	74	5	5	5	3	4	5	5	5	7	0.88	88
	75	5	5	5	4	4	5	5	5	8	1.00	100
	76	5	5	5	3	4	5	5	5	7	0.88	88
	77	5	5	5	4	4	5	5	4	8	1.00	100
	78	5	5	5	4	4	5	5	4	8	1.00	100
	79	5	5	5	4	4	5	5	5	8	1.00	100
	80	5	5	5	4	4	5	5	5	8	1.00	100
	81	5	5	5	4	4	5	5	5	8	1.00	100
	82	5	5	5	3	4	5	5	4	7	0.88	88
	83	5	5	5	3	4	5	5	4	7	0.88	88
	84	5	5	5	3	4	5	5	5	7	0.88	88
	85	5	5	5	4	4	5	5	4	8	1.00	100
	86	5	5	5	4	4	5	5	4	8	1.00	100
	87	5	5	5	3	4	5	5	4	7	0.88	88
	88	5	5	5	3	4	5	5	5	7	0.88	88
	89	5	5	5	4	5	5	5	5	8	1.00	100
	90	5	5	5	4	4	5	5	5	8	1.00	100
	91	5	5	5	4	4	5	5	5	8	1.00	100
	92	5	5	5	3	4	5	5	4	7	0.88	88
	93	5	5	5	4	4	5	5	5	8	1.00	100
	94	5	5	5	3	4	5	5	4	7	0.88	88
	95	5	5	5	3	4	5	4	4	7	0.88	88
	96	5	5	5	4	4	5	4	4	8	1.00	100
	97	5	5	5	3	5	5	5	4	7	0.88	88
	98	5	5	5	3	4	5	5	5	7	0.88	88
	99	4	5	5	2	4	5	5	4	7	0.88	88
	100	5	5	5	2	4	5	5	4	7	0.88	88
	101	5	5	5	3	4	5	5	4	7	0.88	88
	102	5	5	5	3	4	5	5	4	7	0.88	88
	103	5	5	5	3	4	5	5	4	7	0.88	88
	104	5	5	5	3	4	5	5	4	7	0.88	88
Veterinary Pharmacotherapy (Skills)	105	5	5	5	5	5	5	5	5	8	1.00	100
	106	5	5	5	5	5	5	4	5	8	1.00	100
	107	5	5	5	4	5	5	5	5	8	1.00	100
	108	5	5	5	4	5	5	3	5	7	0.88	88
	109	5	5	5	5	4	5	5	5	8	1.00	100
	110	5	5	5	5	4	5	5	4	8	1.00	100
	111	5	5	5	4	5	5	5	5	8	1.00	100
	112	5	5	5	4	4	5	5	4	8	1.00	100
	113	**5**	**5**	**5**	**3**	**3**	**5**	**5**	**4**	**6**	**0.75**	**75**
	114	5	5	5	4	4	5	5	4	8	1.00	100
	115	5	5	5	4	3	5	5	4	7	0.88	88
	116	5	5	5	3	4	5	5	4	7	0.88	88
	117	5	5	5	4	5	5	5	5	8	1.00	100
	118	5	5	5	4	5	5	5	5	8	1.00	100
	119	5	5	5	4	5	5	5	4	8	1.00	100
	120	**5**	**5**	**5**	**3**	**3**	**5**	**5**	**4**	**6**	**0.75**	**75**
	121	5	5	5	3	4	5	5	4	7	0.88	88
	122	5	5	5	4	4	5	5	5	8	1.00	100
	123	5	5	5	4	4	5	5	4	8	1.00	100
	124	5	5	5	3	4	5	5	5	7	0.88	88

Delphi Round 1											
Training programme for pharmacists in veterinary pharmaceutical sciences (Regulation of Veterinary Medicinal Products)											
	Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Expert 7	Expert 8	Number in agreement	Consensus	% Consensus
Regulation of Veterinary Medicinal Products (Aims)	125	5	5	5	4	5	5	5	5	8	1.00	100
	126	5	5	5	4	4	5	5	5	8	1.00	100
	127	5	5	5	4	5	5	5	5	8	1.00	100
	128	5	5	5	4	5	5	5	5	8	1.00	100
	129	5	5	5	4	4	5	5	5	8	1.00	100
	130	5	5	5	4	5	5	5	5	8	1.00	100
Regulation of Veterinary Medicinal Products (Knowledge and Understanding)	131	5	5	5	4	5	5	5	5	8	1.00	100
	132	5	5	5	3	4	5	5	5	7	0.88	88
	133	5	5	5	3	4	5	5	5	7	0.88	88
	134	5	5	5	3	4	5	5	5	7	0.88	88
	135	5	5	5	4	5	5	5	5	8	1.00	100
	136	5	5	5	2	5	5	5	4	7	0.88	88
	137	5	5	5	3	4	5	5	4	7	0.88	88
	138	3	5	5	4	5	5	5	5	7	0.88	88
Regulation of Veterinary Medicinal Products (Skills)	139	5	5	5	3	4	5	5	5	7	0.88	88
	140	5	5	5	4	5	5	5	5	8	1.00	100

Appendix 7

Aims and learning outcomes revised or omitted from the Training Programme for Pharmacists in Veterinary Pharmaceutical Sciences

Aim or learning outcome	Modification/Omission
Discuss the most common renal conditions in companion animals	Omission: a similar learning outcome was accepted
Identify symptoms that may be associated with different stages of chronic kidney disease	Omission: a similar learning outcome was accepted
Discuss the most common gastrointestinal disorders in companion animals	Omission: a similar learning outcome was accepted
Discuss the zoonotic potential of parasites affecting the gastrointestinal tract	Omission: it was deemed more important to focus on parasites in general. Such a learning outcome was accepted.
Discuss the most common respiratory conditions that affect companion animals.	Omission: a similar learning outcome was accepted
Discuss the common dental disorders in companion animals and how these relate to dental disorders in humans	Omission: a similar learning outcome was accepted
To impart a working knowledge of the disease states to consider the significant variations between species in medical therapy of companion animals versus humans and to learn techniques do prescription review, counselling, and advice.	Omission: a similar aim was accepted
Educate pet owners about the importance of prevention against parasites	Omission: a similar learning outcome was accepted
Counsel pet owners on the expected signs and symptoms of the various stages of kidney disease.	Modification: reworded to read ‘Counsel pet owners on signs and symptoms of kidney disease.’

Appendix 8

Training Programme for Pharmacists in Veterinary Pharmaceutical Sciences

Training Programme for pharmacists in veterinary pharmaceutical sciences

The training programme is intended for pharmacists who wish to develop skills/competencies in veterinary pharmaceutical sciences. It provides a comprehensive overview on the most important aspects of veterinary pharmacy. The training programme focuses on three main areas, namely (1) veterinary disease states; (2) veterinary pharmacotherapy and (3) legal and regulatory considerations in veterinary pharmacy practice.

The veterinary pharmacotherapy section includes pharmacotherapy management for all the veterinary disease states mentioned. Additionally, and an introduction to pharmacotherapy in food-producing animals, equine species and exotic animals is presented.

Veterinary Disease States

Description:

The information on veterinary disease states provides details on ten common disease states affecting companion and food-producing animals. This includes their pathology, signs and symptoms, diagnosis, pharmacotherapeutics and prognosis. It also provides an overview of how these conditions relate to the human equivalent. Parasite infestations and antimicrobial resistance and their impact on public health are also discussed.

Veterinary disease states include:

- Behavioural disorders
- Pain management

- Endocrine disorders
- Renal disorders
- Cardiovascular disorders
- Gastrointestinal disorders
- Respiratory disorders
- Dental disorders
- Ophthalmic disorders
- Dermatological conditions

The module aims to:

- Introduce pharmacists to the most common disease states in companion animals.
- Introduce pharmacists to differences in anatomy and physiology between humans and non-human species and their role in different disease states.
- Impart a working knowledge of the disease states to consider the significant variations between different species and humans and to learn techniques for counselling and advice.
- Emphasise challenges attributed to the diagnosis of certain conditions seen in companion animals due to their inability to describe symptoms.

The aims of these modules will be achieved by giving an overview of the most important aspects of the different disease states including their prevalence in different species, aetiology, pathophysiology and diagnoses, and how these relate to the human equivalent. Challenges encountered while diagnosing, managing or treating various disease states are highlighted . Students will learn how to recognise signs of pain, discomfort or abnormal behaviour which may be indicative of underlying conditions such as

osteoarthritis, gastrointestinal conditions, renal or cardiac disorders, and behavioural disorders. The zoonotic potential of certain parasites, bacteria and fungi will be discussed including their impact on public health. Students will be made aware of the implications of antibiotic and antiparasitic resistance, their impact on public health and global initiatives in place to fight these emerging threats. Further detail on important aspects to be discussed are included in the description of the individual topic.

Behaviour disorders

Behavioural disorders in animals vary between species (Overall, 2019). Behavioural patterns change with age. Canine and feline behavioural changes may be physiological or cognitive and both are subject to treatment and intervention (Hammerle et al., 2015).

Common behaviour issues include separation anxiety, generalised anxiety disorder, phobias from certain noises, aggression and profound fears (Overall, 2019; Hammerle et al., 2015). Aggression, most commonly caused by fear, occurs when an animal growls, snaps or bites (Hammerle et al., 2015). Elimination disorders in cats are characterised by changes in their urination patterns and inappropriate urination (Hammerle et al., 2015; Overall, 2019). This can be a behavioural problem or a symptom of an underlying medical condition (Hammerle et al., 2015). Separation anxiety occurs when companion animals are separated from their owner. It presents as signs of clinical distress and is treated medically (Hammerle et al., 2015). Loud noises such as thunder, fireworks or storms can cause anxiety and profound fears that are characterised by trembling, hiding, pacing and destructiveness (DePorter, 2012; Hammerle et al., 2015).

The occurrence of behavioural problems in companion animals has strong animal welfare implications (Fatjó, 2006). Behavioural problems such as canine aggression can be serious public health concerns and play an important role in elective euthanasia and abandonment of companion animals (Fatjó, 2006).

Pain in veterinary patients

The physiology of pain in animals is similar to that seen in humans. (Kukanich, 2019). In human medicine, assessment of pain is dependent on a description by the patient (Walsh, 2016). This is not possible in veterinary patients. In animals it is even more challenging to assess pain due to instinctual survival behaviours that are triggered when they feel pain (Kukanich, 2019). Additionally, different species adapt to pain in different ways. Assessing pain in animal patients greatly relies on observations of behaviour by the veterinary surgeon as well as the pet owners' knowledge of their pet's normal behaviour in stress-free situations (Epstein et al., 2015; Walsh, 2016; Hernandez-Avalos et al., 2019).

Pain management in animals extends beyond the use of medication. As in humans, weight loss, maintaining the ideal body weight and exercise reduces the risk of developing intervertebral disc disease in predisposed dog breeds and development and progression of osteoarthritis (Kukanich, 2019). Physical rehabilitation, acupuncture, and environmental modification are additional non-pharmacological ways to manage pain (Epstein et al, 2015).

Osteoarthritis is a progressive, degenerative, debilitating and painful disease that affects dogs over one year of age (Bhathal et al., 2017, Cuervo, 2020). All dogs are affected by

this condition, but large dog breeds tend to have more severe clinical signs and symptoms (Bhathal et al., 2017). Osteoarthritis leads to functional limitation and causes chronic pain (Bhathal et al., 2017; Kukanich, 2019). Signs include lameness, joint swelling, muscle atrophy and scarring of the joint membrane (Harari, 2020).

Hip dysplasia is the most common developmental orthopaedic condition in dogs and is more common in large breed dogs (Harari, 2020; Cuervo, 2020). Patients with mild dysplasia, or those that cannot undergo surgery, may benefit from weight reduction and restriction of exercise on hard surfaces, physical therapy and pharmacological therapy (Harari, 2020). Surgical interventions can reduce pain and arthritis, and this can include total hip replacement (Harari, 2020).

Endocrine disorders

Companion animals, particularly dogs and cats, are susceptible to similar endocrine disorders that affect humans (Kooistra, 2009). Common endocrine disorders in humans include diabetes mellitus, thyroid disorders and disfunction of the hypothalamic-pituitary-adrenal axis (Mealey, 2019). Thyroid gland dysfunctions and endocrine pancreas are common in dogs and cats. Dysfunction of the hypothalamic-pituitary-adrenal axis is common in dogs, ferrets and horses but is less common in cats (Mealey, 2019).

Diabetes mellitus is a common disease in cats and closely resembles type 2 diabetes in humans (Kooistra, 2009). Diabetes usually occurs in dogs between 5 and 12 years of age and certain breeds are predisposed to diabetes (Catchpole et al., 2005). Type 2 diabetes does not occur in dogs and diabetic dogs are completely insulin dependent (Catchpole et

al., 2005; Frankel, 2016; Mealey, 2019). The most common cause of death in diabetic animal patients is elective euthanasia (Mealey, 2019).

Hyperthyroidism commonly occurs in middle-aged to older cats but is rarely observed in dogs, while hypothyroidism is common in dogs and rare in cats (Mealey, 2019; Peterson, 2012; Kooistra et al., 2009). There is no obvious breed predisposition to thyroid disorders (Peterson, 2012). Clinical signs of hyperthyroidism in cats are similar to those seen in humans with thyrotoxicosis (Mealey, 2019).

Hyperadrenocorticism, or Cushing's Disease, is a common endocrine disorder in dogs but rarely occurs in cats, (Kooistra et al., 2009; Mealey, 2019). Clinical signs in dogs include polyuria, polydipsia, a 'pot belly', alopecia and muscle wasting. The low-dose dexamethasone suppression test is the screening test of choice for canine hyeperadrenocorticism (Greco, 2020).

Renal disorders

Renal diseases are common in companion animals. The aetiology, pathophysiology and treatment share some similarities with human renal disease (Bartges, 2019). Pathophysiological processes that result in acute or chronic renal disease include degenerative, anatomic, metabolic, neoplastic, infectious/inflammatory and toxic/traumatic conditions (Bartges, 2019).

Chronic kidney disease is progressive and results in serious morbidity and mortality in cats and dogs (McGrotty, 2008). Consequences of chronic kidney disease include renal secondary hyperparathyroidism, hypertension, anaemia, proteinuria, metabolic acidosis,

gastrointestinal signs, hypokalaemia, dehydration, and bacterial urinary tract infection in cats. (McGrotty, 2008). In contrast to humans, diabetes mellitus is not a cause of chronic kidney disease in dogs and cats (Bartges, 2019).

In animals, the calculation of the Glomerular Filtration Rate (GFR) from creatinine is not performed, as is done in humans, as the correlation with the GFR actually measured is not linear (Cannon, 2016; Bartges, 2019). Elevated serum creatinine is a reliable, indirect marker for GFR despite the effect on non-renal factors such as dehydration and muscle mass have on the serum levels (Cannon, 2016).

There are several drugs that have the potential to cause nephrotoxicity in animals as well as humans. One of the most common causes of renal injury in veterinary patients, including cats, dogs and horses, is the use of Non-steroidal anti-inflammatory drugs (NSAIDs) (McGrotty, 2008; Legatti et al., 2018; Bartges, 2019). Aminoglycoside antibiotics may cause acute kidney injury, especially in the presence of other risk factors. Meloxicam is safer than most NSAIDs for use in cats as it does not rely on glucuronidation for elimination. In human, cyclosporin is nephrotoxic and is a limitation for its long-term use. Nephrotoxicity with cyclosporin is very rare in dogs and cats (Bartges, 2019).

Cardiovascular disorders

Many of the congenital and acquired cardiovascular diseases that affect humans also affect animals (Lahmers, 2019). One exception is ischaemic heart disease as it very rarely occurs in animals (Lahmers, 2019). In veterinary species, most of the non-infectious heart diseases are familial and strongly associated with the type of breed of the

animal (Lahmers, 2019). Degenerative heart disease is a common cause of heart disease and congestive heart failure in dogs (Boswood et al., 2016; Gordon et al., 2017). It frequently affects older, small breed dogs, but some dog breeds are more susceptible to developing this condition (Gordon et al., 2017).

Atrial fibrillation is a common arrhythmia seen in small animals as a result of atrial enlargement secondary to congenital or acquired heart diseases (Lahmers, 2019). Thromboembolism is a common and detrimental complication of heart disease in cats and is associated with a high mortality rate (Bédard et al., 2007; Koors and Marshall, 2010; Lahmers, 2019). In contrast, dogs with cardiovascular disease do not have an increased risk of thromboembolic complications (Lahmers, 2019).

Gastrointestinal disorders

Cats and dogs experience diseases of the gastrointestinal (GI) tract, that are similar to those in humans, that can be a result of inflammation, infection, neoplasia and other aetiologies. Diagnoses that are usually based on clinical symptoms are more difficult to document in veterinary patients as the patient is not able to describe what they are experiencing (Willard, 2019).

Gastro-oesophageal reflux disease, gastric erosion and ulceration are common conditions in animals (Tolbert et al., 2017). Conditions of the GI tract, liver, gall bladder or pancreas that cause symptoms of abdominal pain or nausea but no obvious clinical signs, (such as vomiting and diarrhoea) are likely to go undetected in animal patients unless the condition progresses or the pain is severe enough that the owner can detect signs and symptoms (Willard, 2019).

Gastrointestinal disease may also be caused by parasite infestations including hookworms, roundworms and *Giardia* (Fiechter et al., 2012; Willard, 2019). In animals, most gastrointestinal issues that are not due to parasites are not definitively diagnosed (Willard, 2019). Certain breeds of animals are predisposed to GI diseases. Brachycephalic dogs have upper airway anatomical abnormalities that may result in gastrointestinal disease (Kaye et al., 2018).

Respiratory disorders

Many conditions of the respiratory system that affect humans can also affect veterinary patients and the pathophysiologic responses are comparable to humans despite genetic, anatomical, and functional variations between humans and animals (Willard, 2019). These include pneumonia (bacterial, viral fungal and protozoal), non-infectious inflammatory disorders of the trachea and/or bronchi, such as asthma, and pulmonary hypertension.

Some animals are bred for certain physical characteristics. This artificial selection for certain traits results in a number of anatomical abnormalities (Packer et al., 2015; Mealey, 2019). Brachycephalic breeds such as pugs, boxers and Persian cats are susceptible to brachycephalic airway syndrome, which is a condition where abnormalities affect the soft palate, trachea and nasopharyngeal turbinates and the soft tissue blocks the airways during respiration (Packer et al., 2015; Willard, 2019). Dolichocephalic dog breeds, such as greyhounds, have very long faces and are susceptible to nasal cavity tumours (Willard, 2019). Tracheal collapse is a condition that is common in very small dog breeds but rarely occurs in cats (Kuehn, 2020).

Asthma and chronic bronchitis are common in cats (Galler et al.,2013). Upper respiratory tract disease is common in cat populations that are crowded and stressful, such those conditions seen in shelters and sanctuaries. Causative agents include both viruses and bacteria (Lee-Fowler, 2014; Nguyen et al., 2019). Infectious feline upper respiratory tract disease is a common cause of morbidity and mortality among kittens (Sykes, 2014).

Chronic obstructive pulmonary disease (COPD) and cystic fibrosis, contrary to humans, are very rare in cats and dogs (Mealey, 2019). Fungal and parasitic infections are common nasal diseases in dogs but not in humans. This is due to the natural behaviour of dogs who have a tendency to sniff their surroundings (Mealey, 2019).

Dental disorders

Dental disorders, in veterinary patients, are similar to those that occur in humans (Reiter, 2020). Periodontal disease is a major cause of tooth loss in animals. This can be due to a lack of proper oral hygiene, type of breed, genetic factors and diet. Periodontal disease is more common older cats, small breed dogs, narrow-muzzled dogs and brachycephalic breeds (McFadden and Marretta, 2013; Retier, 2020).

Periodontal disease is painful and leads to a reduced appetite and weight loss (Cannon, 2016). It is a risk factor for the development of chronic kidney disease (CKD) in cats, dogs and humans (Cannon, 2016). Proper dental care, including brushing is the standard preventative treatment and can keep the teeth and gums healthy (Stella et al., 2018; Reiter, 2020).

There are two stages of periodontal disease (Stella et al., 2018). Gingivitis is the initial, reversible stage of periodontal disease (McFadden and Marretta, 2013). In gingivitis, the gum becomes inflamed, but the ligaments and bone are not affected. The gums tend to bleed on contact, and bad breath is common. Professional cleaning of the teeth, while under anaesthesia, helps control gingivitis (Reiter, 2020).

In periodontitis, the tissue damage is more severe and includes the gums, ligaments and bone. It is irreversible and results in permanent tooth loss (McFadden and Marretta, 2013; Retier, 2020). Dogs that have a diet that consists of hard kibble have less problems due to the mechanical cleaning effect of the food while it is being chewed. Fractured teeth and jaws often occur following trauma. Severe periodontitis and cancer can weaken the jaw and cause fractures. Fractures of the bone need to be stabilised by the veterinary surgeon (Reiter, 2020).

Ophthalmic conditions

Veterinary species suffer from similar ophthalmic conditions seen in humans, such as glaucoma, conjunctivitis, corneal ulcers, anterior uveitis and cataracts (Alessio and Mealey, 2019). The anatomy of the eye and physiology of the eye and visual system vary between species depending on whether the animal is prey or predator, nocturnal or diurnal and the position of the eyes in the head (Alessio and Mealey, 2019). Some ophthalmic conditions are unique to specific species and specific breeds.

Most animal species have 3 eyelids with the third eyelid containing additional glands that are not present in humans. Prolapse of the third eyelid, termed cherry eye, occurs in dogs

and occasionally cats (Alessio and Mealey, 2019; Gelatt, 2020). If not corrected surgically it can lead to chronic conjunctivitis and ocular discharge (Gelatt, 2020).

Common causes affecting the cornea and conjunctiva in both humans and animals are trauma, infection, allergy and defective tear composition or production. Keratoconjunctivitis sicca is a common condition in dogs that results in chronic conjunctivitis, corneal ulceration and scarring (Williams, 2018; Gelatt, 2020).

Cataracts are common ophthalmic conditions that develop with age in dogs and lead to vision loss. Dogs with diabetes are susceptible to develop cataracts (Raghuvanshi and Maiti, 2013; Alessio and Mealey, 2019)

Dermatological conditions

Inhalant allergy, or atopic dermatitis, is a common disease in dogs and cats, and is an exaggerated inflammatory response to an allergen (Kim et al., 2010; Brar et al., 2017; Gedon, 2018; Jeromin, 2019). Both animals and humans can have a genetic predisposition to develop atopic dermatitis or it can occur due to environmental triggers (Kim et al., 2010). While humans tend to outgrow these allergies, in dogs and cats the clinical manifestations will evolve and worsen throughout the animals' life if the condition is not managed (Jeromin, 2019). Skin barrier dysfunctions are the main contributing factor in the pathogenesis and predisposition of atopic dermatitis (Brar et al., 2017). Since allergic reactions affect the skin, animals tend to lick, or scratch affected areas resulting in tissue damage (Jeromin, 2019).

Feline allergic skin disease is not well-understood (Buckley, 2017). Suggested major external triggers include flea saliva, food and environmental allergens (Buckley, 2017). House dust, house dust mites, pollen from trees, weeds, grass, mould spores and insect antigens are common allergens in dogs (Kim et al., 2010; Brar et al., 2017).

Diseases that may be mistaken for atopic dermatitis include flea-allergy dermatitis, sarcoptic mange (demodicosis), food allergy and dermatophytosis (Jeromin, 2019). Canine demodicosis occurs when mites colonise hair follicles and sebaceous glands (Sudhakara Reddy et al., 2014). The most frequently identified causes in canine food allergies include beef, chicken, eggs, corn, wheat, soy and milk (White, 2020). In cats, fish, beef milk and chicken are among the common causes (White, 2020).

Parasitic disease

Parasitic diseases are caused by arthropods, helminths and protozoans (Pereira et al, 2016). Endoparasites and ectoparasites, including some vector-borne parasites are the cause of significant morbidity and mortality in companion animals (Matos et al, 2015; Pereira et al, 2016). Parasites can affect the human population due to their zoonotic potential. Zoonoses is an environmental and public health threat (Matos et al, 2015; Pereira et al, 2016) and one of the goals of 'One Health'.

The majority of internal helminth parasites are gastrointestinal worms (Langston and Varela-Stokes, 2019). These include roundworms, hookworms and tapeworms and can cause gastrointestinal issues in dogs and cats. Intestinal protozoan infections caused by *Giardia* spp. and *Cryptosporidium* spp. cause gastrointestinal tract disorders and can be zoonotic (Matos et al, 2015; Langston and Varela-Stokes, 2019). Ehrlichiosis,

leishmaniasis and heartworm disease are vector-borne diseases (Matos et al, 2015). Heartworm disease causes infectious cardiovascular disease in veterinary patients and is rarely seen in human medicine (Lahmers, 2019).

Ectoparasites infest the skin of humans or animals. Infestations with ectoparasitic arthropods and nematodes tend to cause intense pruritus and significant discomfort. Mange is a skin condition, caused by mites, that despite being host-specific, can affect other animals and people in contact with them. Ticks are blood-sucking, arachnid, ectoparasites that are common in many geographical locations and can affect both animals and people (Langston and Varela-Stokes, 2019) and can transmit diseases such as ehrlichiosis and Lyme disease (Langston and Varela-Stokes, 2019). Fleas are small wingless insects that feed on animal blood. They can transmit diseases, cause allergies or anaemia (Langston and Varela-Stokes, 2019).

Antimicrobial resistance

Broad-spectrum antibiotics are widely used in small animal practice (Pomba et al, 2017). The emergence of bacteria resistant to the antibiotics currently available is of great concern. Antibiotic resistance and resistance to anti-parasitic drugs are a major threat to human and animal health (Dencker et al, 2016). Other challenges include zoonotic diseases and food-borne diseases. Addressing these threats requires a global, multidisciplinary approach, and is one of the goals of the 'One Health' initiative (Destoumieux-Garzon, 2018 and CDC). 'One Health' recognises that the health of the people is connected to the health of animals as well as the environment.

Learning Outcomes

Knowledge and Understanding

By the end of the modules the pharmacist will be able to:

- Compare and contrast common conditions affecting companion and food-producing animals and how these relate to the human equivalent.
- Discuss common behavioural disorders in animals.
- Identify which behavioural symptoms/changes may be due to an underlying medical condition.
- Discuss signs and symptoms of pain in companion animals
- Discuss conditions that commonly cause pain in companion animals such as osteoarthritis and hip dysplasia.
- Recognise signs and symptoms of osteoarthritis and hip dysplasia.
- Discuss the dangers of administering human OTC medication used for minor ailments to companion animals to manage symptoms of certain diseases such as pain.
- Discuss common endocrine diseases in companion animals
- Describe how endocrine diseases in companion animals relate to similar diseases in humans.
- Identify which endocrine disorders are more common in certain species.
- Compare and contrast aetiology and pathophysiology of renal disorders in companion animals with those found in humans.
- Discuss the most common cardiovascular disorders in companion animals
- Identify signs and symptoms that may be indicative of an underlying gastrointestinal disorder.
- Identify which parasites cause gastrointestinal disorders.

- Discuss the most common respiratory conditions that affect companion animals
- Identify which respiratory disorders are more common in companion animals when compared to humans.
- Identify which breeds are more susceptible to different respiratory disorders based on the shape of the skull.
- Discuss the most common causes of allergies in companion animals
- Discuss the different signs and symptoms of the different allergies in companion animals
- Discuss common internal and external parasite infestations in companion animals and the symptoms associated with different infestations.
- Describe the diagnostic tests available for internal and external parasites
- Discuss the zoonotic potential of parasites and their impact on public health.
- Discuss the most common bacterial infections in companion animals.
- Discuss the most common fungal infections in companion animals.
- Discuss the global threat of antimicrobial and anti-parasitic resistance and the initiative of the 'One Health' concept to combat these threats.

Skills

By the end of the module pharmacists will be able to:

- Provide advice for certain conditions seen in animals, especially those that are common to humans.
- Demonstrate caring attitudes with regards to the illness behaviours exhibited by animals

- Provide advice on the symptoms of behavioural disorders and the importance of ruling out underlying medical conditions that may be causing changes in behaviour.
- Educate pet owners on how to recognise signs of fear, stress, anxiety and noise phobias and how these can be prevented.
- Apply basic principles in the treatment and understanding of endocrine disorders.
- Provide education regarding diabetes to increase the owner's confidence in being able to manage a diabetic pet, which may save the pet's life.
- Advise pet owners against using certain medications without the veterinary surgeon's advice due to nephrotoxicity.
- Provide advice on the common allergies encountered in companion animals and how pet owners may reduce the occurrence in their pets.
- Advise pet owners on how to take care of the teeth of their pets to avoid periodontal disease
- Advise pet owners about the importance of prevention of parasitic infestations.
- Advise pet owners about the zoonotic potential of certain parasites.
- Provide advice regarding the prevention and management of parasitic infestations.
- Provide advice on diagnostic testing that can be performed to confirm or rule out parasitic infestations.

Veterinary Pharmacotherapy

Description:

The section on veterinary pharmacotherapy includes the pharmacotherapy options for ten common disease states affecting companion and food-producing animals. The use and

misuse of OTC. It also includes an introduction to pharmacotherapy in equine species and exotic animals.

The module aims to:

- Introduce pharmacists to key anatomical and physiological differences between humans and non-human species that have implications for drug therapy.
- Give an overview of how different drugs behave in different species, whether any anatomical features may adversely affect drug therapy, how drugs are metabolised in certain species, whether there are any toxicities that are specific to certain species or breeds and whether drugs that have been designed for dissolution and absorption in the human gastrointestinal tract achieve the desired effect in different target species.
- Introduce pharmacists to the most commonly used information resources for veterinary medicine and veterinary pharmacy
- Identify the challenges of extrapolating data from human medicine to veterinary medicine.
- Impart a working knowledge of the disease states to consider the significant variations between species in medical therapy of companion animals versus humans and to learn techniques for prescription review, counselling and advice.
- Possess a working knowledge of the names, mechanism of action, indication, dosing, side effects, safety profiles, monitoring parameters and counselling points for drugs that belong to the same therapeutic classes as those used in humans but may cause severe side effects if administered to humans accidentally

- Give an overview of which over-the counter (OTC) human products may be used in animal species and emphasise the potential toxicity of OTC products used in humans.
- Give an overview of which drugs are most commonly used for the treatment of various diseases in companion animals.
- Emphasise challenges attributed to the treatment of conditions seen in companion animals, companion animals' inability to describe symptoms and challenges pertaining to the administration of medicinal products and monitoring of side effects.

The aims of these modules will be achieved by giving an overview of the most important aspects of pharmacotherapy for the common disease states and how these relate to the human equivalent. Pharmacodynamic and pharmacokinetic differences that influence drug absorption, distribution, metabolism and excretion will be emphasised. Challenges encountered while administering medication, managing conditions, monitoring progression of diseases and monitor for side-effects of medication are highlighted . The students will be introduced to the common veterinary medicinal products used in companion animals and food-producing species. The off-label use of human medicinal products to treat diseases in companion animals is highlighted. The potential risks of using human OTC products in companion animals are emphasised. Students will also be introduced to the pharmacotherapy in food-producing animals, equine species and exotic animals. Further details on important aspects to be discussed are included in the description of the individual topic.

Over-the-Counter products

Many OTC products used for the treatment of minor ailments in humans are potentially toxic to companion animals, even at low doses. Exposure to these products may be intentional or accidental (Khan, 2020). Xylitol, which is common in human OTC products is very toxic to dogs and cats. Paracetamol and NSAIDs that are available OTC are toxic to some species. The amount of paracetamol in one tablet of OTC medication can be fatal to cats and cause serious toxicity in dogs (Frankel et al., 2016). Several OTC antihistamines used for human patients can also be used for veterinary patients. First generation antihistamines (chlorpheniramine, dimenhydrinate and diphenhydramine) can be used in animal patients. Cetirizine, fexofenadine and loratadine can be used for allergies in veterinary patients without causing drowsiness.

It is recommended that human OTC products are to be used in animals only if prescribed by a veterinary surgeon (Davidson, 2016). Pharmacists play an important role regarding OTC use in animal companions to prevent inadvertent poisoning.

Pharmacotherapy of behavioural disorders

Treatment for behavioural disorders does not only involve pharmacotherapy. It is more successful when coupled with behaviour modification training (Overall, 2019). Medications used to treat aggression include tricyclic antidepressants (TCAs), selective serotonin reuptake inhibitors (SSRIs), gabapentin and benzodiazepines such as alprazolam (Hammerle et al., 2015, Overall, 2019).

Prior to managing elimination disorders using medicinal products, any underlying medical condition must be ruled out (Hammerle et al., 2015). Environmental changes

are the first line of treatment. Separation anxiety can be treated using tricyclic antidepressants, such as clomipramine and SSRIs such as fluoxetine (Hammerle et al., 2015; Overall, 2109). Noise phobias are treated with benzodiazepines such as alprazolam for dogs, and clonazepam for cats, ideally administered before an anticipated triggering event (Hammerle et al., 2015; Overall, 2019).

In addition to pharmacotherapy, food or feed constituents may affect behaviour (Kato et al, 2012). Examples include tyrosine, phenylalanine, tryptophan, omega-3 fatty acids and low-protein diets. Prescription diets used to manage anxiety are supplemented with alpha-casozepine and L-tryptophan. The physiological activity of alpha-cosazepine shares similarities with the anxiolytic effects of benzodiazepines (Kato et al, 2012).

Veterinary patients cannot communicate what effect the medication is having on them. It is important that pet owners understand how the medication is exerting its effect, any specific behavioural changes to be expected and how to monitor for side effects (Overall, 2019).

Pharmacotherapy of pain

Effective pain management involves a balanced strategy using different classes of pain modifying drugs that are based on anticipated pain levels and individual pet needs (Epstein, 2015; Walsh 2016).

Oral NSAIDs are the first line treatment for chronic pain (Walsh, 2016). They are commonly used in dogs to treat mild to moderate pain but are less commonly used in cats due to their increased sensitivity to the renal side-effects (Kukanich, 2019).

Parenteral NSAIDs are used for the treatment of moderate to severe pain. NSAIDs suitable for use in animals include caprofen, meloxicam, firocoxib and robenacoxib. Meloxicam is licensed for chronic use in cats (Drozdzynsk and Pelligand, 2016).

Paracetamol has moderate oral bioavailability in dogs and a short half-life. It is rarely used as a sole analgesic but is more commonly used in combination with opioids (Kukanich, 2019). Paracetamol is contraindicated in cats as it is very toxic (Epstein, 2015; Walsh, 2016; Kukanich, 2019).

Opioids are very effective in managing acute, moderate to severe, pain (Epstein, 2015; Drozdzynsk and Pelligand, 2016). The oral bioavailability of opioids is low in dogs and cats. Clinical analgesia is achieved with parenteral administration (Kukanich, 2019). In animals, opioids are considered a safe drug class since the lethal doses are substantially higher than therapeutic doses. In contrast to humans, opioids only produce mild respiratory depression in animals (Kukanich, 2019).

Other drugs used to manage pain include TCAs, serotonergic drugs such as tramadol, gabapentinoids and local anaesthetics may provide analgesia for specific types of pain (Walsh, 2016; Kukanich, 2019. Glucosamine and chondroitin are natural products that are recommended for treating osteoarthritis in dogs (Bhathal, 20 17).

Pharmacotherapy of endocrine disorders

Endocrine diseases in companion animals and humans are similar. The diseases themselves and aspects of treatments differs between species (Mealey, 2019). Pharmacotherapy involves the same classes of drugs as those used in human patients but

pharmacokinetic and pharmacodynamic differences require dose modifications in dogs, cats and other animal species (Mealey, 2019).

Some diabetic cats may be controlled by oral hypoglycaemic medication such as sulfonylureas, similar to those used in human patients (Frankel, 2016; Mealey, 2019). Most diabetic dogs are insulin-deficient. Oral hypoglycaemic drugs are not useful in dogs and require the administration of exogenous insulin (Catchpole et al., 2005). Owner adherence to treatment is imperative to ensure the survival of diabetic pets (Gilor, 2019).

Successful treatment of diabetic patient depends on dietary management and frequent monitoring (Peterson, 2020). Involving the pharmacist in the management of diabetes can enhance the owner's ability to manage the disease.

The treatment for hypothyroidism is levothyroxine. Levothyroxine doses in dogs are much higher than those prescribed for humans since the bioavailability of levothyroxine is low and the clearance rate is faster (Mealey, 2019). Treatment of hyperthyroidism includes radioiodine, chronic antithyroid medication and life-long iodine-deficient diet (Peterson, 2020). Carbimazole is an antithyroid drug which is converted to methimazole after administration and blocks thyroid-hormone synthesis (Peterson, 2020). Propylthiouracil is not recommended for use in cats due to the high incidence of side effects (Peterson, 2020).

Hyperadrenocorticism can be treated surgically or pharmacologically. The veterinary-approved drug trilostane (an adrenal enzyme inhibitor) is commonly used in the treatment of Cushing's disease (Mealey, 2019; Greco, 2020).

Pharmacotherapy of renal disorders

Pharmacological treatment in kidney disease is multifactorial and symptomatic. The goals of chronic kidney disease management are to minimise electrolyte and metabolic by-product excesses and deficits to improve the quality of life of the animal (Bartges, 2019).

Patients with renal disease can exhibit gastrointestinal symptoms. Histamine-2 receptor antagonists are administered to inhibit gastric acid secretion (McGrotty, 2008; Bartges, 2019); maropitant is an antiemetic that is administered if the patient is vomiting (McGrotty, 2008; Bartges, 2019); appetite stimulants such as mirtazapine may be used. The goal of therapy with renin-angiotensin-aldosterone system (RAAS) inhibitors (enalapril, benazepril) and calcium channel blockers (amlodipine) is to decrease the systolic blood pressure and relieve systemic arterial hypertension that occurs as a consequence of chronic kidney disease (McGrotty, 2008; Bartges, 2019). ACE inhibitors are the drug of choice in patients with persistent renal proteinuria (McGrotty, 2018). RAAS inhibitors are usually associated with GI upset and hyperkalaemia. Diuretics are not commonly used as they can cause dehydration and electrolyte imbalances (Bartges, 2019).

Dietary modification to therapeutic kidney diets increases survival time and decreases the risk of uraemic crisis (McGrotty, 2008; Bartges, 2019). They are specially formulated to be replete in potassium and water-soluble vitamins, contain omega-3 fatty acids, have lower amounts of protein, phosphorus and sodium content and have alkalinising effects (Bartges, 2019). Renal diets targeted towards felines are supplemented with potassium (McGrotty, 2008).

Renal replacement therapy, such as dialysis, is not widely available for veterinary patients (Bartges, 2019). In acute kidney injury, for many nephrotoxins, the only available option is supportive care. Without renal replacement therapy, many dogs and cats with acute kidney injury are euthanised or die from complications (Bartges, 2019).

Pharmacotherapy of cardiovascular disorders

Asymptomatic congestive heart failure is not treated with any medication (Gordon et al., 2017). Symptomatic congestive heart failure is managed with diuretics (furosemide, torasemide), ACE inhibitors (enalapril, benazepril), aldosterone inhibitors (spironolactone) and the inodilator pimobendan. Pimobendan provides a positive inotropic and vasodilatory effect (Hägstromm et al., 2008; Lahmers, 2019). The combination of pimobendan with an ACE inhibitor improves clinical signs and quality of life (Hägstromm et al., 2008).

Animal patients experience the same arrhythmias as humans. Tachyarrhythmias are managed medically with beta-blockers (atenolol, propranolol) (BSAVA, 2017; Lahmers, 2019). Systemic hypertension also occurs in veterinary patients and is managed with calcium channel blocker amlodipine in cats (BSAVA, 2017; Lahmers, 2019). In contrast to humans and cats, thromboembolic consequences of cardiovascular disease rarely occur in dogs. Platelet inhibitors such as clopidogrel are used to reduce the risk of thrombosis in cats as its efficacy is superior to that of aspirin (BSAVA, 2017; Lahmers, 2019).

Pharmacotherapy of gastrointestinal disorders

While the same nomenclature for common GI diseases is used (e.g. inflammatory bowel disease, and gastric ulceration/erosion) the actual disease and the management may be different (Willard, 2019). Caution must be exercised when extrapolating from human medicine to veterinary medicine.

Proton pump inhibitors (omeprazole, pantoprazole) have superior acid-supressing activity and are the treatment of choice for erosive oesophagitis and for the treatment or prevention of gastric ulceration/erosion (Tolbert et al, 2011; Golly et al., 2018). Famotidine is widely used in veterinary medicine due to its immediate clinical relief and administration with food (Tolbert et al, 2017; Golly et al., 2018).

Maropitant is a very effective antiemetic used in cats and dogs to prevent emesis associated with various aetiologies ranging from chemotherapy-induced nausea and vomiting to motion sickness (Sedlacek, 2008; Willard, 2019).

Antidiarrhoeal opiates are rarely indicated in small animals (Willard, 2019). Metronidazole is indicated in chronic, antibiotic-responsive small-bowel enteropathy, feline irritable bowel syndrome and for the treatment of giardiasis (Sekis et al, 2008; Willard, 2019). Metoclopramide is an effective prokinetic and is used to enhance intestinal motility of both the small and large intestine.

Anti-parasitic drugs such as fenbendazole and praziquantel can be used in combination with antibiotics to manage GI diseases resulting from parasite infestations (Fiechter et al., 2011; Willard, 2019). Antidiarrhoeal drugs are rarely prescribed. Probiotics are used

in the management of acute diarrhoea. Laxatives used for the treatment of constipation include lactulose and paraffin oil (Willard. 2019).

Pharmacotherapy of respiratory disorders

Non-pharmacological management of respiratory diseases includes avoiding any known allergens, minimising environmental pollutant and dietary measures to treat or prevent obesity (Mealey, 2019).

Broad-spectrum antibiotics are used if bacterial infections are involved (Kuehn, 2020). Doxycycline is the first line antibiotic in animals with acute bacterial upper respiratory tract infections (Lappin et al., 2017). Asthma in humans and the respective reactive airway diseases in dogs and cats are treated similarly. Corticosteroids (inhaled or systemic) are used to treat airway inflammation and bronchodilators are used when required (Galler et al., 2013; Mealey, 2019). As with human patients, the adverse effects of corticosteroids increase with the dose and duration of treatment. Side effects of corticosteroid used are similar to those experienced by humans. One difference is that osteoporosis does not seem to be a common sequela of steroid use in dogs and cats (Mealey, 2019).

Opioids are the only class of drugs that are effective for suppressing cough in animals (Dowling, 2020). Coughing in cats tends to be a sign of underlying disease. Rhinitis is usually caused by an underlying condition. Nasal decongestants are rarely prescribed to veterinary patients (Mealey, 2019). The therapeutic index of systemic decongestants, such as pseudoephedrine, is narrow in dogs and cats and therefore should not be

administered (Mealey, 2019). Pulmonary hypertension is treated with sildenafil (Bach, 2006).

Pharmacotherapy of ophthalmic conditions

Advanced disease may require surgical treatment but routine pharmacotherapy involves the use of topical ophthalmic preparations. Most medicinal products used to treat corneal/conjunctival disease in companion animals are human medicinal products that are used off-label (Alessio and Mealey, 2019).

The goal of pharmacological treatment of glaucoma is to reduce the intraocular pressure and subsequently decrease the risk of nerve damage. Veterinary surgeons use human medicinal products off label to treat glaucoma. Carbonic anhydrase inhibitors (brinzolamide, dorzolamide), beta-blockers (timolol) and prostaglandins (latanoprost) are the most frequently prescribed drugs to treat glaucoma in dogs, cats and horses (Alessio and Mealey, 2019).

Treatment of conjunctivitis depends on the underlying cause. Common drugs prescribed for the treatment of conjunctivitis include cyclosporin, artificial or natural tears, antibiotic solutions or ointments and ophthalmic corticosteroids (Williams, 2018; Alessio and Mealey, 2019). Corticosteroids are contraindicated in the presence of corneal ulcers. Analgesia is an important in the treatment of corneal diseases.

Systemic absorption of drugs administered topically to the eye may result in systemic side effects. Since most dogs and cats weigh substantially less than humans, this route

of administration, particularly with human medicines, can result in pharmacologic concentrations of the drug in the systemic circulation (Alessio and Mealey, 2019).

Management of allergies

Clinical management of allergies involves modulation of the immune response and repair of the defective skin barrier (Jeromin, 2019).

The main goal of pharmacotherapy in atopic dermatitis is to control the itching (Jeromin, 2019). Corticosteroids are used to control the symptoms in atopic dermatitis (Gedon and Mueller, 2018). Despite their effectiveness in modulating the immune response, long-term use of injectable glucocorticoids is not recommended in dogs (Livry et al., 2015; Gedon and Mueller, 2018; Jeromin, 2019; Moriello, 2020). Short-acting corticosteroids like prednisone or methylprednisolone are preferred over dexamethasone which is longer-acting (Jeromin, 2019). Cats treated with corticosteroids are more at risk of developing diabetes mellitus (Lowe et al., 2009; Jeromin, 2019).

Antihistamines (cetirizine, chlorpheniramine, diphenhydramine, and loratadine) can be used for management of the condition but are not effective in acute flare-ups. OTC combination products that include analgesics and/or decongestants must not be used. Topical treatment prevents percutaneous absorption of the allergen and prevents secondary bacterial and yeast overgrowth (Jeromin, 2019). Topical treatment is used less frequently than in humans due to the presence of a hairy coat and issues with compliance (Gedon and Mueller, 2018). In dogs and cats, the physical removal of allergens by bathing in hypoallergenic shampoos or rinsing/wiping fur after the animal has been outside can be helpful (Olivry et al., 2015; Jeromin, 2019).

In humans with atopic dermatitis, polyunsaturated fatty acids have been reported to modulate the inflammatory response. Similarly, in dogs, polyunsaturated fatty acids decrease inflammation and pruritus (Bauer, 2011; Jeromin, 2019). Dietary omega-3 or omega-6 fatty acids can be an adjunct to treatment. Commercially available diets formulated for allergic animals are supplemented with polyunsaturated fatty acids and are helpful in treating symptoms. Allergen desensitisation, where the animal is desensitised to the allergen, is a curative treatment option (Gedon and Mueller, 2018).

Pharmacotherapy of infectious diseases

Antimicrobial therapy in animal patients follows the same principles as those for treating infections in human patients. The most common pathogens causing infection differ between species (Papich, 2019). It is important that the concentration of the drug attained at the site of infection is sufficient. Pharmacokinetics and pharmacodynamics of antimicrobial agents are different in different species, and different species are susceptible to different side effects. The dose, frequency and method of administration must be chosen such that the chance of a cure is maximised, while prevent relapse and minimising the risk of developing resistance (Papich, 2019; Boothe, 2020). Antibiotics such as cephalosporins, fluoroquinolones, macrolides, penicillins, tetracylcines and aminoglycosides are used to treat infections in both human and veterinary patients (Dencker et al, 2016).

Antifungal drugs are used in all veterinary species including mammals, fish, reptiles and birds (Papich, 2019). Skin infections are treated using topical applications. There are few veterinary antifungal drugs and veterinary surgeons prescribe antifungals intended for use in humans for the treatment of companion animals (Papich, 2019). The most

common antifungal drugs used are the azole antifungal drugs such as ketoconazole and itraconazole. Terbinafine is an antifungal which is active against yeasts and a wide range of dermatophytes (Papich, 2019).

Antiviral drugs have a very small role in treating disease when compared to their role in human medicine (Papich, 2019). Most antivirals used in humans are designed for specific disease states such as HIV, hepatitis C and herpes virus, which do not occur in animals (Papich, 2019). Non-specific antiviral drugs intended for use in humans are very toxic to animal patients. Acyclovir is very toxic to cats. Antivirals agents are mostly used topically to treat ophthalmic herpes infections (Papich, 2019).

Pharmacotherapy of parasitic diseases

Common internal parasites of small animals are helminths which includes nematodes (roundworms, hookworms and whipworms), cestodes and trematodes (Langston and Varela-Stokes, 2019). Anthelmintic drugs are used to treat or prevent helminth infections. Few anthelminthic drugs have a broad-spectrum of action against all types of endoparasites (Langston and Varela-Stokes, 2019). Products may contain multiple products against a variety of endoparasites and ectoparasites, usually in the form of a single product against nematodes combined with treatment for fleas or ticks. There is concern that these products may give rise to parasite-resistance (Langston and Varela-Stokes, 2019). The benzimidazole class of drugs includes fenbendazole, mebendazole and albendazole. They are widely used antiparasitic drugs in both small and large animals (Langston and Varela-Stokes, 2019). Fenbendazole is commonly used to treat giardiasis in dogs and cats due to its high therapeutic index and low incidence of side effects.

Fipronil is a topical insecticide, usually used in the form of spray or spot-on solutions, directly applied onto the skin. It is effective against ticks and fleas. Praziquantel is used in the treatment of tapeworm infestation in small animals (Langston and Varela-Stokes, 2019). Fluralaner and afoxolaner are available as chewable tablets and are used in the treatment of ectoparasites namely ticks and fleas. Differences in the elimination half-life allows for monthly dosing for afoxolaner versus three-monthly dosing for fluralaner (Langston and Varela-Stokes, 2019). Spinosad is used in the control of fleas in dogs and cats in tablet-form. Imidacloprid is a spot-on solution used for the treatment of fleas (Langston and Varela-Stokes, 2019).

Routinely, puppies and kittens should be treated with anthelmintic drugs due to exposure or infection during gestation or immediately after birth (Langston and Varela-Stokes, 2019). Prophylaxis against endoparasites and ectoparasites is important in controlling the transmission of endemic, emergent or re-emergent parasites (Matos et al, 2015). Companion animals should be given prophylactic treatment at the prescribed intervals. Intervals are set taking into account the cycle of the parasites (Matos et al, 2015).

Pharmacists play a role in educating pet owners on the importance of parasite prevention and their zoonotic potential. Pharmacists are aware of the interpretation of drug labels in relation to efficacy against parasites and safety of the drug in young animals (Langston and Varela-Stokes, 2019).

Introduction to food-animal pharmacotherapy

Food-producing animals are those animals from which edible products are harvested. These are milk, eggs, honey and meat from muscle organs. Cattle, pigs, chickens,

turkeys, sheep, goats, and food fish should always be considered as food-producing animals (Fajt, 2019). Animals such as rabbit, pheasant and quail are sometimes hunted or raised for food and might be considered as food-producing animals under those circumstances (Fajt, 2019).

Drug disposition is different between monogastric species (such as humans, pigs and companion animals), ruminants (cattle, goats and sheep) and monogastric birds (poultry). These differences in dissolution, disintegration and gastric emptying impact both the drug regimen and the withdrawal period (Toutain et al., 2010; Fajt, 2019). The ruminant digestive system presents challenges to drug absorption and metabolism (Vandamme and Ellis, 2004). The rumen can affect drug absorption rates and bioavailability after oral dosing (Vandamme and Ellis, 2004; Fajt, 2019). Elimination half-lives and metabolic pathways differ between ruminants and non-ruminants and between different ruminants. Dosage regimens calculated based on extrapolation based on elimination rates of another species is not possible, even if both are ruminants (Fajt, 2019). Drug distribution into milk is a concern for dairy cattle and goats due to the exposure to drugs via milk or dairy products (Fajt, 2019).

Common diseases in food-producing animals include infectious respiratory disease, mastitis, skin and soft-tissue infections, GI parasites and ectoparasites. Since food animals are often raised in herds or flocks, disease challenges often affect the entire herd of flock. This requires drug administration via water or food to ensure that all the animals are dosed (Fajt, 2019).

Introduction to equine pharmacotherapy

The selection of an appropriate dosage regimen is attributed to variations in the anatomy, physiology, biochemistry, behaviour of different species and the condition affecting the animal (Toutain et al., 2010). Pharmacokinetic and pharmacodynamic variations determine the sensitivity to the drugs administered (Jerzsele, 2012). There are significant differences in the pharmacokinetics of administered drugs between horses and humans, and horses and other companion animals (Davis, 2019).

The oral drug absorption of many drugs is lower in horses when compared to other species due to the length and volume of the gastrointestinal tract (Jerzsele, 2012; Davis, 2019). The gastric pH of horses is highly variable, the volume of fluid available for dissolution is much larger than that of humans and feeding alters the gastric emptying rate (Davis, 2019).

Drug metabolic pathways in horses are less well-defined. The expression of CYP450 enzymes varies in horses (Nebbia et al., 2003). Animals with larger body weights have a lower cardiac output and a lower maximum clearance of drugs (Davis, 2019).

Antibacterials commonly cause enterocolitis due to disruption of the normal microflora (Toutain et al., 2010). The oral absorption of drugs such as amoxicillin, amoxicillin clavulanate and cefalexin is too low to reach therapeutic concentration in adult horses. They also present a higher risk of development of diarrhoea so their use in horses is limited (Toutain et al., 2010; Davis, 2019). Doxycycline is the most common antibiotic used in horses. Intravenous administration of doxycycline, at any dose, can cause cardiac arrhythmias and possible sudden death. Enrofloxacin is a safe antibiotic in adult horses

but can cause cartilage damage in young, growing animals. In contrast to dogs and cats, paracetamol is very safe to use in horses (Davis, 2019). In horses, aminoglycosides exhibit age-dependent pharmacokinetics. Doses for neonatal foals are much higher than those for adults due to the higher volume of distribution in foals (Davis, 2019).

Dexamethasone and prednisolone are the corticosteroids that are more commonly prescribed for use in horses (Davis, 2019). NSAIDs are used in the management of acute conditions, such as colic and fever, and chronic conditions such as osteoarthritis (Donnell and Frisbie, 2014; Davis, 2019). Antihistamines such as cetirizine, chlorpheniramine and hydroxyzine can be used in the treatment of dermatitis (Olsén et al., 2011; Davis, 2019). Proton pump inhibitors are preferred over H_2-receptor antagonists for the treatment of gastric ulcers. Dopamine is used to treat Cushing's disease in horses due to a different pathophysiology of the disease (Davis, 2019).

Pharmacotherapy of exotic animals

The pharmacotherapy of small exotic animals, including rabbits, hamsters, rats, mice, guinea pigs and birds, is challenging and unique (Wiebe and Eichstadt Forsythe, 2019). Diagnosis of disease, stress of handling and administering medication are common problems encountered when treating exotic animals (Meredith, 2010). Disease prevention is thus very important. The oral route of administration is the easiest. Subcutaneous and intramuscular injections are also limited by the amount of volume that can be administered (Wiebe and Eichstadt Forsythe, 2019). Most drugs used for exotic animals are used off-label (Wiebe and Eichstadt Forsythe, 2019).

Common disorders seen in pet rodents (hamsters, mice, rats and guinea pigs) involve traumatic injuries from fighting with cage mates or predators, nutritional deficiencies and infectious diseases. Dermatological disorders in rodents may be due to ectoparasites, bacterial and fungal organisms and skin disorders secondary to endocrine diseases (Meredith, 2010). Skin disorders may be secondary to environmental and behavioural conditions (Meredith, 2010).

Diagnosis of disease is difficult in rabbits. Rabbits are prey animals and hide any signs of illness. They may have severe illness before they are given treatment (Mäkitaipale et al., 2015). Rabbits are herbivores with a very sensitive gastrointestinal tract that relies on consistent microbiota and complex intestinal contractions. Drugs that disrupt the function of the digestive tract can be fatal to rabbits (Wiebe and Eichstadt Forsythe, 2019). Their microflora differs to that of omnivores. Antibiotic agents used to treat omnivores are not safe for herbivores. Antibiotic choices are limited in rabbits. Clindamycin, amoxicillin, amoxicillin-clavulanic acid, ampicillin, erythromycin and cephalosporins cause enteritis (Fann and O'Rourke, 2001; Wiebe and Eichstadt Forsythe, 2019). Antibiotics considered safe for rabbits include metronidazole, chloramphenicol, sulphonamides and fluoroquinolones (Wiebe and Eichstadt Forsythe, 2019).

NSAIDs, such as meloxicam, are used for chronic pain and inflammation in rabbits (Dykes and Orr, 2001; Wiebe and Eichstadt Forsythe, 2019). Rabbits are hosts for a number of external parasites such as fleas, ticks, mites and lice. Fleas can be treated by using flea preventives labelled for cats. Fipronil, an agent commonly used in topical flea and tick preventatives, cannot be used in rabbits (Wiebe and Eichstadt Forsythe, 2019).

Avian species are more similar to their distant reptile counterparts rather than to mammals. Birds have unique gastrointestinal, urogenital and reproductive tracts. All birds lack teeth and their sharp beaks make it challenging to administer oral medication (Louchart and Viriot, 2011; Wiebe and Eichstadt Forsythe, 2019). Birds can be treated by adding medication to their food or drinking water. This method is less stressful but can result in subtherapeutic doses being administered as sick birds tend to eat and drink less (Wiebe and Eichstadt Forsythe, 2019; Staff, 2020). Medication can be administered directly into the mouth using a dropper or syringe (Staff, 2020). Birds are commonly treated for bacterial, fungal and parasitic diseases. Respiratory, gastrointestinal, urinary tract, reproductive tract and skin infections are common (Wiebe and Eichstadt Forsythe, 2019).

Behavioural problems such as feather plucking have been treated with neuroleptics and antidepressants such as fluoxetine, amitriptyline, clomipramine and haloperidol. Veterinary fluoroquinolones (enrofloxacin and marbofloxacin) can be administered to adult birds but should not be used in young birds. Amoxicillin/clavulanic acid is commonly used for respiratory or skin infections. Giardiasis is treated with metronidazole. Ivermectin and fenbendazole are effective for treating roundworms. Midazolam, diazepam and potassium bromide can be used for treating seizures in birds (Wiebe and Eichstadt Forsythe, 2019).

Learning Outcomes

Knowledge and Understanding

By the end of the module pharmacists will be able to:

- Identify and discuss the challenges pet owners face when administering medication to animals
- Discuss the differences in pharmacotherapeutic options between humans and animals.
- Discuss the implications of pharmacodynamic and pharmacokinetic differences on drug disposition between species.
- Identify how different drugs behave in different species, whether any anatomical features may adversely affect drug therapy, how drugs are metabolised in certain species, whether there are any toxicities that are specific to certain species or breeds and whether drugs that have been designed for dissolution and absorption in the human gastrointestinal tract achieve the desired effect in different target species.
- Compare and contrast the most common disease states in companion and food-producing animals with emphasis on pharmacotherapy decision making.
- Discuss the different challenges presented by different species of animals with respect to administration of medication.
- Recognise the risks that aver the counter drugs pose to companion animals and recognise those which are relatively safe.
- Identify which ingredients in food and medicinal products are toxic to certain species and what can lead to inadvertent poisoning.
- Discuss the role of behaviour modification and the role of pharmacotherapy in the management of behaviour disorders.
- Discuss the pharmacological management of behavioural disorders.
- Discuss the pharmacotherapeutic options for the management of pain in companion animals.

- Discuss the role of various analgesics used in the management of pain in companion animals.
- Discuss the most commonly prescribed NSAID therapy options for the treatment of degenerative joint disease in dogs and cats.
- Discuss the potential benefits of supplements in the management of chronic conditions that cause pain.
- Explain the most common therapies used in the treatment of common endocrine disorders.
- Discuss treatment options for diabetes in companion animals.
- Discuss treatment options for thyroid disorders in companion animals.
- Discuss the pharmacotherapy of renal disorders.
- Discuss treatment options for kidney disease and associated symptoms.
- Identify those drugs which are nephrotoxic to different species of animals.
- Discuss pharmacotherapeutic options for cardiovascular disorders.
- Discuss the pharmacotherapeutic management of gastrointestinal disorders.
- Discuss the importance of dietary changes and the use of specially-formulated diets in the management of gastrointestinal disorders.
- Discuss the pharmacotherapy of respiratory disorders.
- Discuss the role of antibiotics in the treatment of respiratory disorders.
- Identify and discuss adverse effects associated with the use of steroids for the management of respiratory disorders.
- Discuss the pharmacotherapy of ophthalmic disorders.
- Discuss the importance of systemic absorption of topical ophthalmic preparations intended for use in humans.
- Discuss different pharmacotherapeutic options for the treatment of allergies.

- Discuss the advantages and disadvantages of topical treatment in animal patients.
- Discuss the role of commercially available diets and the role of polyunsaturated fats in the management of allergies.
- Discuss immunotherapy as a treatment option for the treatment of allergic disorders.
- Discuss the principles of treating infections in veterinary patients.
- List the most common antimicrobial agents, anti-fungal and anti-protozoal agents used in the treatment and control of infections.
- Discuss the most common anti-infective agents used in animals.
- Discuss the most common antifungal drugs used in animal patients.
- Discuss the role of antiviral drugs in veterinary patients.
- Discuss common treatment options for different parasite infestations taking into consideration the needs of the animal.
- Identify differences between different anti-parasitic drugs
- Explain what is meant by food-producing animals and its implications in treatment and drug administration.
- Identify which animals are considered as food-producing animals.
- Explain that pharmacological management of diseases in food-producing is different to treating companion animals and is tightly-regulated.
- Identify and explain differences in drug administration to horses due to their different absorption, distribution, metabolism and excretion of medicinal products.
- Identify which animals are classified as exotic animals.
- Discuss the challenges when administering medicine to exotic animals.
- Describe common conditions seen in pet rodents.
- Discuss pharmacotherapeutic options for conditions in pet rodents.

- Discuss the implications of pharmacodynamic and pharmacokinetic differences on drug disposition between rabbits and humans.
- Describe common conditions that occur in birds and their pharmacotherapeutic options.

Skills

By the end of the module pharmacists will be able to:

- Safely dispense medicinal products for use in animals.
- Provide the correct pharmaceutical care and monitoring
- Offer rational and evidence-based advice to veterinary surgeons who wish to use human medicinal products in animals.
- Communicate effectively with owners and veterinary surgeons to increase access to medicinal products by appropriate counselling, enhancing medication compliance, solve drug administration challenges and recommend appropriate pharmacotherapy choices
- Advise human caregivers about any possible risks from administering or inadvertent us of veterinary drugs.
- Take an evidence-based approach when making decisions and answering questions concerning animal patients.
- Educate pet owners and prevent them from inadvertently poisoning their pets by treating them with inappropriate and potentially toxic human OTC products.
- Educate pet owners on how to administer medication to animals and what can be done in difficult patients.
- Provide advice on different treatment options for parasitic infestations
- Educate pet owners on how to prevent or be prepared for certain behaviour disorders

- Educate pet owners to recognise signs and symptoms that may be indicative of underlying disease or adverse reaction to medication.
- Educate pet owners to understand what effect the medication is expected to have and how to monitor for side effects.
- Educate owners on the goals of diabetes management and the importance of adherence to treatment and monitoring to increase the chances of successful management of a diabetic pet.

- Counsel pet owners on the use of dietary supplements for the management of certain conditions.
- Advise owners on the importance of renal diets or low protein diets in the management of renal diseases
- Advise owners that misuse of medicinal products that are nephrotoxic can result in kidney damage.
- Advise owners on the importance of dietary changes in the management of gastrointestinal disorders.
- Educate pet owners on the potential toxicity of OTC products in companion animals

Regulation of veterinary medicinal products

This module aims to:

- Introduce the directives, regulations and guidance related to the development, manufacture and distribution of veterinary medicinal products, including the evolution of laws governing veterinary medicinal products both at a European and National level.

- Outline key differences in regulation between veterinary and human medicinal products (food-producing and performance animals – withdrawal periods)
- Discuss the pharmacist's contribution in veterinary pharmaceutical regulatory affairs
- Give an overview of the Maltese veterinary practice scenario especially with respect to dispensing drugs for use in animals.
- Introduce off-label use of human medicinal products in veterinary patients.
- Build a working knowledge of regulatory aspects of drug use in animals and instil a sense of ethical responsibility in decision making regarding veterinary drug use.

An introduction to the regulation of veterinary medicinal products and its historical background is presented. The similarities and differences between the regulation of human medicinal products and veterinary medicinal products are presented. This includes quality, safety and efficacy with emphasis on food-producing species. Key differences in the regulation between veterinary and human medicinal products are presented, with emphasis on demonstrating the safety of any residues, in food, from medicinal products that are administered to food-producing animals. The objectives and importance of regulation in the pharmaceutical field and how it impinges on the practice of veterinary pharmacy are highlighted.

Within the European Union (EU) the regulation of veterinary medicinal products falls under Directive 2001/82/EC. Directive 2001/82/EC has been transposed into Subsidiary Legislation 437.47 Veterinary Medicinal Products Regulation, under in Maltese Law. The regulations within this law apply to all veterinary medicinal products in Malta. This also includes pre-mixes for medicated feeding stuffs that are intended to be placed onto

the Maltese market, and are prepared by methods involving one or more industrial processes.

When administered to food-producing animals, veterinary medicinal products may leave residues in foodstuffs. The residues are pharmacologically active substances, excipients, degradation products or metabolites that may be harmful to humans. European law requires that foodstuffs such as meat, milk or eggs must not contain residues that may represent a hazard to human health.

Learning outcomes

Knowledge and Understanding

By the end of the module pharmacists will be able to:

- Describe the main pharmaceutical regulations, directives and guidance documents which manufacturers and wholesalers are expected to abide by when producing or distributing veterinary medicinal products in the European union.
- Describe the main differences in the requirements for marketing authorisations between human medicinal products and veterinary medicinal products. (into consideration clinical trials and differences in the dossier)
- Follow regulations and guidance when providing veterinary medicinal products to animals intended to be used as food or performance animals (e.g. racing horses) and be aware of any penalties in this regard. This includes the requirement of any withdrawal periods necessary when medicinal products are administered to food-producing animals.

- Discuss the importance of keeping toxic drug residues out of the food supply and be aware of any prohibited off-label use of certain drug and drug classes for food-producing animals.
- Familiarise pharmacists with the laws and regulations regarding the practice of pharmacy with respect to using human OTC drugs in animals
- Discuss the regulation of veterinary and human medicinal products with respect to quality standards of safety and effectiveness studies and standards for manufacture of veterinary medicinal products.
- Discuss the key differences between human and veterinary medicinal products including the number of species regulated, number of animals used in field studies, ethical considerations, and the need to demonstrate human food safety for medicinal products used in food-producing animals
- Discuss the pharmacist's contribution in pharmaceutical regulatory affairs

Skills

By the end of the module pharmacists will be able to:

- Interpret veterinary pharmaceutical regulations, directives and guidance which manufacturers and wholesalers are expected to abide by when producing or distributing veterinary medicinal products in the European union.
- Dispense human or veterinary medicinal products in accordance with common veterinary practices and in line with the regulations, including the need of withdrawal periods when medicinal products are to be used in food-producing animals.

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Appendix 9

Amendments to Directive 2001/82/EC and S.L.437.47

Amendments to Directive 2001/82/EC

Amendment	Date	Amending Directive/ Regulation	Description
M1	2004	Directive 2004/28/EC	Amendments concern definitions given by article 1 to that Directive in order to determine the application scope, marketing authorisation and applications to obtain such authorisations. This is due to the possibility of free movement of goods within member states.
M2	2009	Commission Directive 2009/9/EC	Replaces text in Annex I. Annex I lays down the requirements and analytical protocol, safety tests, pre-clinical and clinical analyses of veterinary medicinal products.
M3	2009	Regulation (EC) No 470/2009	Establishes residue limits of pharmacologically active substances in foodstuffs of animal origin. Puts in place methodological principles for the scientific risk assessment and risk management recommendations that are to be applied by EMA when preparing opinions on the maximum residue limits (MRLs) of pharmacologically active substances which may be permitted in food of animal origin under that regulation.
M4	2009	Directive 2009/53/EC	Amends Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products.
M5	2009	Regulation (EC) No 596/2009	Adapts a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny. It lays down the procedures for the exercise of implementing powers conferred on the Commission, with regard to the regulatory procedure with scrutiny.

Amendments to S.L. 437.47 of the laws of Malta

Date	Legal Notice	Corresponding amendment in Directive 2001/82/EC	Description
2006	L.N. 82 of 2006	M1	Inserts new provisions which widen the application scope and sets out new measures as regards the authorisation required to place veterinary medicinal products on the market
2009	L.N. 23 of 2009	N/A	Inserts sub-article (2) in article 60. These provisions specify criteria that must be fulfilled by veterinary medicinal products for food-producing to be exempted from the requirement to be dispensed only against a veterinary prescription.
2009	L.N. 60 of 2009	M2	Amends the Veterinary Medicinal Products Regulations by replacing the text in the Schedule. This sets chemical, pharmaceutical and analytical standards and lays down provisions on safety and residue tests and preclinical and clinical trials in respect of testing of veterinary medicinal products.

Appendix 10

The Content Validity Index (CVI) validation method: I-CVI and Ave-CVI values for NCA-Q

Expert Validation of the NCA-Q									
Validation domain: Relevance to research									
	Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Number in agreement	I-CVI
Section A	1	5	5	5	5	5	5	6	1.00
	2	5	5	5	5	5	5	6	1.00
	3	5	5	4	5	5	5	6	1.00
	4a	5	5	4	5	5	5	6	1.00
	4b	5	5	5	5	5	5	6	1.00
	5a	5	5	5	5	5	5	6	1.00
	5b	5	5	5	3	5	5	5	0.83
	6	5	5	5	5	5	5	6	1.00
	7	5	5	5	5	5	5	6	1.00
	8	5	5	5	5	5	5	6	1.00
Section B	9	5	5	5	5	5	5	6	1.00
	10	5	5	5	5	5	5	6	1.00
	11	5	5	5	5	5	5	6	1.00
	12	5	5	5	5	5	5	6	1.00
	13a	5	3	5	5	5	5	5	0.83
	13b	5	5	5	3	5	5	5	0.83
	14a	5	5	5	5	5	5	6	1.00
	14b	5	5	5	5	5	5	6	1.00
	15	5	5	5	5	5	5	6	1.00
	16a	5	5	5	5	5	5	6	1.00
	16b	5	5	5	5	5	5	6	1.00
	17	5	5	5	5	5	5	6	1.00
Section C	18	5	5	5	5	5	5	6	1.00
	19	5	5	5	5	5	5	6	1.00
	20a	5	5	5	5	5	5	6	1.00
	20b	5	5	5	5	5	5	6	1.00
	21a	5	5	5	5	5	5	6	1.00
	21b	5	5	5	5	5	5	6	1.00
	22	5	5	5	5	5	5	6	1.00
Section D	23a	5	5	5	5	5	5	6	1.00
	23b	5	5	5	5	5	5	6	1.00
	23c	5	5	5	5	5	5	6	1.00
								Ave-CVI	0.98

Expert Validation of the NCA-Q									
Validation domain: Clarity of questions and statements									
	Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Number of agreement	I-CVI
Section A	1	5	5	5	5	5	5	6	1.00
	2	5	5	5	5	5	5	6	1.00
	3	5	5	5	5	5	5	6	1.00
	4a	5	5	5	5	5	5	6	1.00
	4b	5	5	5	5	5	5	6	1.00
	5a	5	5	5	5	5	5	6	1.00
	5b	3	5	4	1	5	5	4	0.67
	6	4	5	3	5	5	5	5	0.83
	7	5	5	5	5	5	5	6	1.00
	8	4	5	5	5	5	5	6	1.00
Section B	9	5	5	5	5	5	5	6	1.00
	10	5	5	5	5	5	5	6	1.00
	11	5	5	5	5	5	5	6	1.00
	12	5	5	5	5	5	5	6	1.00
	13a	5	3	5	5	5	5	5	0.83
	13b	5	5	5	2	5	5	5	0.83
	14a	5	5	4	5	5	5	6	1.00
	14b	5	5	5	5	5	5	6	1.00
	15	5	5	5	5	5	5	6	1.00
	16a	5	5	5	5	5	5	6	1.00
	16b	5	5	5	5	5	5	6	1.00
	17	5	5	5	5	5	5	6	1.00
Section C	18	5	5	5	4	5	5	6	1.00
	19	5	5	5	5	5	5	6	1.00
	20a	5	5	4	5	5	5	6	1.00
	20b	5	5	5	4	5	5	6	1.00
	21a	5	5	4	5	5	5	6	1.00
	21b	5	5	4	5	5	5	6	1.00
	22	5	5	5	5	5	5	6	1.00
Section D	23a	5	5	5	5	5	5	6	1.00
	23b	5	5	4	5	5	5	6	1.00
	23c	5	5	5	5	5	5	6	1.00
								Ave-CVI	0.97

Expert Validation of the NCA-Q									
Validation domain: Structure and layout of questionnaire									
	Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Number of agreement	I-CVI
Section A	1	5	5	5	5	5	5	6	1.00
	2	5	5	5	5	5	5	6	1.00
	3	5	5	5	5	5	5	6	1.00
	4a	5	5	5	5	5	5	6	1.00
	4b	4	5	5	5	5	5	6	1.00
	5a	5	5	5	5	5	5	6	1.00
	5b	4	5	5	1	5	5	5	0.83
	6	5	5	5	4	5	5	6	1.00
	7	5	5	5	5	5	5	6	1.00
	8	3	5	3	5	5	5	4	0.67
Section B	9	5	5	5	5	5	5	6	1.00
	10	5	5	5	5	5	5	6	1.00
	11	5	5	5	5	5	5	6	1.00
	12	5	5	5	5	5	5	6	1.00
	13a	5	5	4	5	5	5	6	1.00
	13b	5	5	5	5	5	5	6	1.00
	14a	5	5	5	5	5	5	6	1.00
	14b	5	5	5	5	5	5	6	1.00
	15	5	5	5	5	5	5	6	1.00
	16a	5	5	5	5	5	5	6	1.00
	16b	5	5	5	5	5	5	6	1.00
	17	5	5	5	5	5	5	6	1.00
Section C	18	5	5	5	3	5	5	5	0.83
	19	5	5	5	5	5	5	6	1.00
	20a	5	5	5	5	5	5	6	1.00
	20b	5	5	5	5	5	5	6	1.00
	21a	5	5	5	5	5	5	6	1.00
	21b	5	5	5	5	5	5	6	1.00
	22	5	5	5	5	5	5	6	1.00
Section D	23a	5	5	5	5	5	5	6	1.00
	23b	5	5	5	5	5	5	6	1.00
	23c	5	5	5	5	5	5	6	1.00
								Ave-CVI	0.98

Appendix 11

Questionnaire items revised or omitted from the questionnaires for National Competent Authorities (NCA-Q)

Question or statement number	Modification/Omission
8	Modification: Extensive modification to the options given to include the ability to select a percentage that reflects the workload for each of the areas.

Question or statement number	Other Comments
14b	Modification: re-worded to improve clarity and structure of the question.
16b	Modification: re-worded to improve clarity and structure of the question.
21b	Modification: re-worded to improve clarity and structure of the question.

Appendix 12

Questionnaire for the Identification of Identification of resources of different EU National Competent Authorities that regulate veterinary medicinal products (NCA-Q)

Identification of resources of different EU National Competent Authorities that regulate veterinary medicinal products

The questionnaire is to be answered by all the National Competent Authorities (NCAs) that have veterinary medicinal products within their remit. Please answer Sections A – C. In those cases where the same NCA is not responsible for both human and veterinary medicinal products please also answer Section D.

Section A: General information		
1	Which areas does your national competent authority (NCA) regulate? Tick all that apply.	□ Human medicines □ Veterinary medicines □ Medical devices □ Cosmetics □ Herbal medicinal products □ Homeopathic products □ Other _____
2	Which of the following services are provided by your NCA?	□ Granting/Withdrawal of licenses/Variations □ Monitoring safety of medicines □ Overseeing of clinical trials □ Monitoring sales of antimicrobial agents □ Granting of permissions for compassionate use □ Medicines intelligence and access □ Medicines information □ Scientific Advice □ Regulatory Advice □ Inspections □ Other _____
3	Does your NCA regulate both human medicines and veterinary medicines?	□ Yes □ No
4a	Are the services offered for the sector of veterinary medicines the same as those for human medicines?	□ Yes □ No
4b	If no, please outline the main differences	
5a	Is there a dedicated unit/department that offers services solely for the veterinary sector?	□ Yes □ No
5b	Provide a brief description of the organisation of those who offer services in the sector of veterinary medicinal products.	
6	Are the personnel specifically trained in the area of veterinary medicines to be able to provide the above-mentioned services?	□ Yes □ No

7	Personnel within the unit/department, or individually offering services for the veterinary sector have which of the following areas of expertise? Tick all that apply. If not in the list, please include the area in 'Other'.	□ Veterinary medicine □ Pharmacy □ Pharmacology □ Toxicology □ Microbiology □ Biochemistry □ Chemistry □ Biology □ Mathematics □ Statistics □ Other _____
8	What percentage of the total workload from the following areas concerns veterinary medicinal products?	□ Granting/Withdrawal of licenses/Variations _____ □ Monitoring safety of medicines _____ □ Overseeing of clinical trials _____ □ Monitoring sales of antimicrobial agents _____ □ Granting of permissions for compassionate use _____ □ Medicines intelligence and access _____ □ Medicines information _____ □ Scientific Advice _____ □ Regulatory Advice _____ □ Other _____
Section B: Assessment of Veterinary Medicinal Products		
9	Are assessments for veterinary medicinal products carried out in your NCA?	□ Yes □ No
10	For which type of authorisation/s are the assessments carried out?	□ Central authorisation □ Mutual recognition procedures □ Decentralised procedures □ National authorisation □ Other
11	For which of the following types of veterinary medicinal products are assessments carried out?	□ New chemical entity □ Generic products □ Biologicals □ Vaccines □ Similar biologicals □ Immunological products □ Radiopharmaceuticals □ Homeopathic products □ Other _____
12	Are assessments for veterinary medicinal products carried out by assessors solely dedicated to assessing veterinary medicinal products?	□ Yes □ No

13a	Do the assessors require any prior qualifications/training in veterinary therapeutics to be able to assess veterinary medicinal products?	□ Yes □ No □ Depends on the type of assessment
13b	Provide a brief description of your reasoning.	
14a	Does your NCA provide training for the assessment of veterinary medicinal products?	□ Yes (go to Q14b) □ No
14b	What type of training is given?	□ Internal training □ External training □ Specific courses/conferences □ Training provided by other assessors □ Other _____
15	Please provide a short description of the areas in which an assessor must be trained in order to be able to assess veterinary medicinal products.	
16a	Does your NCA use external experts to assess veterinary medicinal products?	□ Yes (go to Q16b) □ No
16b	Which parts of the assessment are carried out by external experts?	□ Non-clinical □ Quality □ Clinical □ Safety □ Other _____
17	Why does your NCA require the use of external experts?	□ Required expertise not available within the NCA □ No adequately trained personnel employed with NCA □ Workload is sometimes too heavy so additional help is required □ Workload not enough to be able to require someone solely dedicated to that task □ Other _____
Section C: Medicines Information, Intelligence and Access		
18	Does your NCA offer a service of 'Medicines Information' for veterinary medicinal products?	□ Yes □ No
19	Briefly describe the role/responsibility of the department/section/ unit/ division or personnel providing this service.	

20a	Do those offering this service require any prior qualifications/training in veterinary therapeutics?	□ Yes □ No □ Depends
20b	Please provide a brief description of your reasoning.	
21a	Is training provided by your NCA for this role?	□ Yes (go to Q21b) □ No
21b	What type of training is given?	□ Internal training □ External training □ Specific courses/conferences □ Other _____
22	Regarding medicines information, what sources are used to provide the requested information?	
Section D: Collaboration with other NCAs **Where same NCA does not regulate both human and veterinary medicines please answer questions below.**		
23a	Does your NCA communicate, cooperate or collaborate with other NCAs that do not regulate veterinary medicinal products?	□ Yes (go to Q23b and Q23c) □ No
23b	What is/are the other NCAs responsible for?	□ Human medicines □ Medical devices □ Cosmetics □ Herbal medicinal products □ Homeopathic products □ Other _____
23c	In which of the following areas does your NCA collaborate/cooperate with other NCAs?	□ Good regulatory practices in the field of medicines □ Help with assessments of veterinary medicinal products □ NCAs invite each other's staff as observers/additional attendees when attending meetings/seminars or conferences □ Sharing correspondence in relation to common areas of interest □ Include members of the NCA responsible for human medicines for courses organised by the EU-NTC (Network training centre) for veterinary medicinal products and vice versa □ Sharing reports concerning respective stakeholders (assuming appropriate consent granted) □ Comment on respective Standard Operating Procedures, work

	procedures, application forms intended for stakeholders □ Access to network infrastructure □ Consultation with each other □ Other

Thank you for your participation.

Appendix 13

Proposal for the establishment of Veterinary Medicines Support Office

Proposal for a Veterinary Medicines Support Office

The proposal is for a support office within a regulatory entity specialised in human medicinal products to extend its services to veterinary medicinal products. Services considered are the assessment of veterinary medicinal products and medicines information. The proposal is based on data and feedback obtained from the NCA-Q and the analysis of the regulatory framework. The data is supplemented by material from published literature and information that is available for the public.

Purpose

The Veterinary medicines support office aims to protect and enhance animal health through the scientific assessment of veterinary medicines and an evidence-based provision and dissemination of information. Entities specialised in the regulation of medicinal products for human use, gain a plethora of experience in the field of scientific assessment of medicinal products and medicines information. This knowledge can be combined with training to extend the services to the field of veterinary medicines.

The objectives of the veterinary medicines support office are envisaged to be:

- To carry out the scientific assessment which reviews quality, safety and efficacy for veterinary medicinal products following procedures line with the European legislation.
- To ensure the safety and efficacy of authorised veterinary medicinal products.
- To provide a service of drug information.

Setup

The setup of the support office will include the necessary human resources including managerial, technical and administrative members to fulfil its function. It is being proposed that a quality system is established within the support office. A quality management system helps coordinate and direct an organization's activities to meet the requirements and improve its effectiveness and efficiency on a continuous basis. Audits of the quality system ensure that there is a system of continuous development (Simmons, 2004; ISO, 2015).

Assessment of veterinary medicinal products

Decisions on the authorisation of medicinal products are based on an objective, scientific assessment of the quality, safety and efficacy (EMA, 2020a). During assessments it is determined whether a medicinal product meets the necessary quality, safety and efficacy requirements and that it has a positive risk-benefit balance in favour of the animal population it is intended for (EMA, 2020b).

The veterinary medicines support office, through training and in collaboration with other entities, is envisaged to have the capacity to assess EU type dossiers. Assessors within an entity specialised in human medicinal products have extensive knowledge of human medicine assessments. Assessments include quality, non-clinical, clinical and safety aspects of a medicinal product. Assessors with a pre-existing, extensive knowledge in these areas would be easier to train due to the similarity between the processes and procedures for human and veterinary medicinal products.

Parts 1,2 and 3 of a dossier for veterinary medicinal products includes administrative information, quality aspects such as chemical, pharmaceutical and biological documentation and safety and residues documentation (EC, 2015). These may be assessed by assessors working in both human and veterinary medicinal products or who possess the knowledge of the same areas with respect to human medicinal products.

Part 4 of the dossier for veterinary medicinal products includes pre-clinical and clinical data. This includes bioequivalence, bioavailability, dose determination, dose confirmation, laboratory studies or clinical field trials. These aspects are very specific and may require expertise in veterinary medicine for assessment.

Assessors with a specific expertise to assess a dossier of a veterinary medicinal product can be from the same entity granting an authorisation or an independent member. Independent members are also called external experts. External experts provide scientific expertise upon request (EMA 2020c). External experts may be employed for services where specific expertise is required and cannot be obtained such as assessment of specific parts of the dossier for which expertise is not available within the support office.

Involvement withing the European Medicines Agency

The Committee for Veterinary Medicinal Products (CVMP) is the committee, within the European Medicines Agency (EMA), responsible for veterinary medicinal products. The CVMP has the responsibility to grant marketing authorisations for veterinary medicinal products. The CVMP is the European Medicines Agency's (EMA) committee responsible for veterinary medicines and plays an important role in the authorisation of medicines. The CVMP is also responsible for recommending maximum residue limits (MRLs).

Before a veterinary medicine intended for food-producing animals is authorised in the EU, the CVMP evaluates the safety of its pharmacologically active substances and their residues and recommends MRLs. The MRLs become legally binding food safety standards when accepted by the European Commission. The support office would benefit from attending meetings held by the CVMP.

Medicines information

The aim of medicines information is to compile, produce, evaluate and distribute evidence-based impartial information on medicines to the public, to health care professionals, the veterinary sector and for the needs of public decision-making.

Medicines information is defined as information on medicines and pharmacotherapy available to consumers and health care professionals from various information sources, either in person, in written form or via electronic services (telephone, Internet, television and radio).

Medicines information may be disseminated either through a database or through a website.A database, or register , of veterinary medicinal products may be created and the public may be granted access. The register would include basic data for each medicinal product, for example active substance, pharmaceutical form, strength, information about the marketing authorisation etc. A Summary of Product Characteristics document (SmPC) is provided for each medicine. A website can be instituted to disseminate general information on veterinary medicinal products to the public but no information on individual products is disseminated to the public

The support office may become a contact point for questions related to veterinary medicinal products. This includes questions asked by the veterinary surgeons, other professionals or entities concerning veterinary medicinal products. It is being suggested that the system of providing answers to questions put forward is to prepare evidence-based answers, evidenced by at least two reputable sources, in writing to the entity asking the question.

Training needs

Personnel offering services for veterinary medicinal products may have varying areas of expertise. Specialists in veterinary medicines, pharmacists, specialists in pharmacology, chemistry, biology, biochemistry, toxicology, mathematicians and statisticians may all be valuable in the services being offered in these areas.

Training to be able to carry out assessments on veterinary medicinal products will be required. The procedures and processes for obtaining a marketing authorisation for veterinary medicinal products are similar to those required for human medicinal products. In both dossiers the presence of administrative information, documentation on quality, safety, efficacy, non-clinical and clinical data is required. Veterinary medicinal products require additional safety and residue tests. Specific training areas include quality, safety and residues. Personnel already trained or possessing pre-existing knowledge on human medicinal products would be easier to train. Since Part 4 of the dossier for veterinary products is the non-clinical and clinical data, specific expertise in the field of veterinary medicine is required.

Training may be provided by assessors already specialised within the area. Since the support office is to be established within an entity specialised in human medicine, training may be delivered by assessors forming part of, or rendering services to entities specialised in veterinary medicinal products. External training may be utilised if assessors specialised in veterinary medicinal products are not available. Training on the required areas may be acquired by attending specific courses or conferences.

The EU Network Training Centre (EU NTC) is a joint initiative between the Heads of Medicines Agency (HMA) and the EMA. The aim of the EU-NTC is to ensure that good scientific and regulatory practices are spread across the EU medicines agencies regulatory network along with harmonised training standards, through the provision of high quality and relevant training shared through a European central platform. The EU-NTC offers training courses involving the regulation of veterinary medicinal products in the form of webinars and organised training events (HMA and EMA, 2015).

Cooperation/collaboration with NCA for veterinary medicines

The support office for veterinary medicines is being proposed to be established within an entity specialised in human medicines. It is proposed that the support office will collaborate and cooperate with the entity responsible for regulating veterinary medicinal products and other entities as required. The mutual co-operation in matters relating to human and animal health contribute to the development and wellbeing of society. Enhanced collaboration may also contribute to the improvement of both human and animal health through the improvement of the quality, efficacy and safety of veterinary medicinal products. Areas of cooperation and collaboration include:

i. consultation with each other

ii. the sharing of good regulatory practices in the field of medicines, human and animal health, exchanges of scientific knowledge, good practice and regulatory information

iii. staff of the support office may be invited as observers or as additional attendees when attending meetings and/or seminars and/or conferences that relate to veterinary medicinal products and vice versa

iv. training and education activities. Support office may be invited to participate in the EU NTC for veterinary medicinal products area training and education assessment of applications for Centrally Authorised Products.

v. sharing correspondence in relation to common areas of interest.

vi. access to network infrastructure, knowledge and information.

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Appendix 14

Abstracts for poster submission FIP

SEVILLE 2020
FIP WORLD CONGRESS
13 - 17 September

Pharmaceutical practice:
Academic pharmacy
FIPSUB-1698 /

Education and Training in Veterinary Pharmaceutical Sciences

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My preferred method of presentation is: Poster Presentation
Please fill in the presenting author's organization: Department of Pharmacy-University of Malta

Background: The responsibility to provide high-quality pharmaceutical care for animal patients challenges pharmacist knowledge regarding indications, dosages and drug administration in animals.

Purpose: To develop a training programme for pharmacists in veterinary pharmaceutical sciences.
Methods: Three questionnaires were developed and disseminated to veterinary surgeons, pharmacists and pet owners to identify challenges of access to medicines and the perception and contribution of the pharmacist in the treatment of animals. Data collected was used to design a training programme for pharmacists. The training programme was validated using a modified e-Delphi method.
Results: Respondents consisted of 92 pharmacists, 21 veterinary surgeons and 231 pet owners. Seventeen veterinary surgeons prescribed human medicines for use in animals because the veterinary medicinal product needed was not available. Pharmacists were perceived as unprepared to safely dispense and provide advice for medication use in animals by 61 pharmacists, 16 veterinary surgeons and 122 pet owners. Pharmacists (n=68) and veterinary surgeons (n=16) agreed that pharmacists should be trained in veterinary pharmaceutical sciences. Pet owners (n=171) would be more willing to ask a pharmacist for advice if they can be sure the pharmacist is knowledgeable. The validated training programme consists of three main areas, namely veterinary disease states, veterinary pharmacotherapy, and regulation of veterinary medicinal products.
Conclusion: The perception on the skills of pharmacist with regards to veterinary pharmaceutical care remains a challenge and a barrier to optimise veterinary pharmacy services.

SEVILLE 2020
FIP WORLD CONGRESS
13-17 September

Pharmaceutical practice:
Social and administrative pharmacy
FIPSUB-1696 /

Pet Owner Perception of the Role of the Pharmacist in Animal Care

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My preferred method of presentation is: Poster Presentation
Please fill in the presenting author's organization: Department of Pharmacy-University of Malta

Background: Pharmacists are uniquely positioned to counsel pet owners and collaborate with veterinary surgeons to provide the best care for animal patients.
Purpose: To identify the pet owner's perception of the role of the pharmacist in animal care.
Methods: A questionnaire was developed, validated and disseminated to pet owners using social media platforms. The questionnaire consisted of 3 sections: Section A: Demographic data Section B: Challenges and barriers of access to medicines and good animal care and Section C: Perception of pharmacist interventions and the contribution towards the treatment of animals.
Results: Two hundred and thirty-two pet owners answered the questionnaire. Fifty percent (n=116) agreed that pharmacists have the knowledge to give advice regarding human medicine use in animals. Fifty-three percent (n=122) disagreed that pharmacists can give advice on chronic medical conditions that affect their pets. Ninety-one percent (n=208) prefer to ask the veterinarian for advice rather than the pharmacist. Seventy-five percent (n=172) would be more willing to go to a pharmacist for advice if they can be sure pharmacists are knowledgeable and skilled with respect to animal care. Eighty-three percent (n=193) would like community pharmacies to stock veterinary medicines. Other services suggested by pet owners included urine testing (n=114), compounding medicinal products (n=94) and glucose checks (n=87) for their pets.
Conclusion: Considering that 83% of pet owners would like pharmacies to stock veterinary products shows that access to medicines needs to be improved. The lack of trust towards pharmacists perceived by 53% of respondents indicates that pharmacists should strengthen their role with pet owners.