

Canadian Animal Health Market Update: Companion animals are getting a lot of attention during COVID-19

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The COVID-19 pandemic has drastically changed all aspects of our lives since March 2020, including work. According to Statistics Canada, 32% of Canadians worked from home in January 2021, as compared to only 4% in 2016. This trend is likely to continue after the pandemic, with 80% of respondents indicating their preference to continue working at least half their hours from home post-COVID-19, and 15% preferring to work all their hours from home.

Pets everywhere

Work from home has led to an explosion in pet adoption. 18% of Canadian pet owners acquired their companion during the pandemic. In 2021, over half of Canadians own a pet, with the greatest pet ownership among those aged 18-24. In one survey, 77% of North American veterinary clinics reported having more patients than they did before the pandemic. As work-from-home arrangements continue to expand, pet ownership will also continue to rise. This is good news for all involved in Canadian animal health.

Pet insurance growing rapidly

With rising pet ownership comes increasing expenditures on veterinary services. Emergency veterinary care can be very expensive, however, leading more pet owners to turn to pet insurance. The North American Pet Health Insurance Association (NAPHIA) reported that the North American pet insurance industry surpassed USD2.17 billion in premiums paid in 2020. In Canada, NAPHIA members reportedly sold \$244.6 million in premium, a 17.2% increase over the previous year. This growth rate surpassed the prior year's growth, which was also in the double digits. It is estimated that the Canadian pet insurance market will expand by a compound annual growth rate (CAGR) of 7.4% through 2027. Pet insurance is a net benefit to all companion animal health companies.

Pet insurance spotlight

In April 2021, Merck Animal Health's HomeAgain and Pethealth Inc.'s PTZ Pets Plus Us[®] Insurance Agency Ltd. announced a partnership to provide pet insurance under the Pet Plus Us[®] brand.

Companion animal drug product submissions and approvals are up

During this pandemic, companies have continued to file veterinary drug submissions, and

Health Canada has continued to approve a record number of veterinary drug products by way of notice of compliance (NOC). [1] Over the last 18 months, there was a 33% increase in overall veterinary drug New Drug Submissions as compared to the previous period.[2] The number of companion animal drug approvals, although small, increased by 60%.[3]

The Health Canada pathway to veterinary drug approval, which results in the issuance of a NOC, may be more expensive but it allows the sponsoring manufacturer to manage competitive entry, including by listing issued Canadian patents onto the Patent Register.

Consistent with rising consumer demand for veterinary services, trade research organizations project an increase in the market for veterinary drug products. For example, the veterinary health market for eye disorders in animals is expected to see a compound annual growth rate (CAGR) of 5.7% over the next five years. Grand View Research estimates that the global companion animal healthcare market will surpass \$37 billion USD by 2028 given the rise in pet adoptions, the rise in chronic disease in pets, the rise of online pharmacies, and increased pet insurance demands. These trends are expected to also be reflected in Canada.

New drug spotlight

Librela® (*bedinvetmab*)

In February 2021, Zoetis Canada obtained a NOC and data exclusivity for Librela®, an injectable monoclonal antibody for the treatment of osteoarthritis pain in dogs. This NOC also relates to a so-called “innovative drug” entitled to data protection.

NexGard® Combo (*eprinomectin, praziquantel, afoxolaner*)

In January 2021, Boehringer Ingelheim obtained NOC approval for NexGard® Combo, for use in the treatment of feline parasites.

Solofer (*iron (iron dextran complex)*)

In February 2021, Pharmacosmos obtained NOC approval for Solofer, a medication aimed at combatting iron deficiency in swine and piglets.

Cardalis® (*spironolactone, benazepril hydrochloride chewable tablets*)

In July 2020, Ceva Santé Animale obtained FDA approval for Cardalis®, a combination drug for the treatment of atrioventricular valvular insufficiency (AVVI). Cardalis® is not currently approved in Canada.

Consolidation of Canadian veterinary practices

The U.S. trend towards large scale consolidation of, and investment in, veterinary practices hit a new high in Canada in 2020. In July 2020, U.S. private equity firm Berkshire Partners acquired a 70% stake in VetStrategy in a transaction valued over \$1.4 billion. VetStrategy is a consolidator of veterinary practices across Canada. Its business model involves buying veterinary clinics from practitioners who are retiring or who would prefer not to have to deal with the administrative aspect of veterinary practice.

Berkshire Partners’ investment in VetStrategy reflects an implied valuation of about 22 times estimated EBITDA, and optimistic view of the business of veterinary medicine in Canada. Veterinary clinics provide essential services and were not closed during the pandemic. In fact, in the U.S., use of veterinary health services increased during the pandemic while demand for human health care services dropped.

Veterinary practice consolidation is expected to continue. A 2021 report by Veterinary Integration Solutions documents the growing number of consolidators in North America, including Mars, Incorporated – the candy bar giant – and its 2017 acquisition of VCA, which now operates over 1000 veterinary clinics in North America. At least one of these consolidators, Encore Vet Group, is active in Canada (Ontario). According to one estimate, 25% of veterinary practices will be consolidated by 2023, with consolidators representing 50% of total veterinary visits.

Canadian regulations update

A number of recent Canadian regulatory changes are relevant to animal health stakeholders:

- Amendments to the *Food and Drug Regulations (Regulations)* were made to provide an easier path for the importation, sale, and advertisement of veterinary drugs for the treatment of COVID-19.
- The *Regulations* were also amended to make it easier to access veterinary drugs under the Emergency Drug Release (EDR) Program. The amendments allow a practitioner to request access to an unauthorized drug without submitting information on the use, safety and efficacy of the drug when the drug has been previously approved by the EDR Program for the same medical emergency. In addition, drugs for the EDR Program may be imported prior to approval for individual practitioner use, provided a letter of authorization has been issued for the drug.

Health Canada also released its "Forward Regulatory Plan: 2021-2023". This plan proposes a Use of Foreign Decisions (UFD) pathway to streamline the approval process for veterinary health products by allowing manufacturers to rely upon the authorization of a trusted foreign regulator. Health Canada is expected to engage stakeholders in 2021 and open public comment in spring 2022.

Health Canada also launched other public consultations:

- Health Canada has proposed updates to the guidance document "Veterinary drugs – Management of regulatory submissions: Updated guidance for industry". The consultation period for these proposed updates end on July 13, 2021.
- The Public Health Agency of Canada has proposed changes to the "Canadian Biosafety Standard, third edition" (CBS). The changes target Chapters 3 to 5, which deal with the containment, operational practice requirements and performance and verification testing requirements. The consultation period ends on June 15, 2021.

Ongoing monitoring of antimicrobial use

Starting in 2017, amendments to the Canadian *Food and Drug Regulation* came into force to bring oversight to the use of antimicrobials in animal care. Health Canada also moved to designate Medically Important Antimicrobials (MIA), which, as of December 1, 2018, require a veterinary prescription for their use.

In March 2021, Health Canada's Veterinary Drugs Directorate published antimicrobial sales figures from the Veterinary Antimicrobial Sales Reporting (VASR) system for 2018, the first year of Canada's new antimicrobial oversight system. The time required to publish this data illustrates the growing pains of the new framework.

In addition to data gathering, federal, provincial and veterinary medicine stakeholders are now focused on education. The 2021 federal budget proposed providing \$28.6 million over five years to the Public Health Agency of Canada, Health Canada, and the Canadian Food Inspection Agency, to help address antimicrobial resistance, specifically support efforts to prevent the inappropriate use of antimicrobials and expand efforts to monitor the emergence of antimicrobial resistance. Provincial veterinary medical association are actively involved in similar efforts.

Veterinary drug class action authorized in Québec

Class actions remain rare in the animal health industry but in November 2020, the Québec Superior Court authorized a class proceeding against Intervet on behalf of Québec dog owners for damages suffered as a result of their dogs' treatment with BRAVECTO® (fluralaner). It is alleged that fluralaner caused various health conditions in the dogs, for which the defendants failed (allegedly) to provide warning. Key among the issues at authorization (certification) was whether the *Québec Consumer Protection Act* applies to the sale of veterinary drugs by a veterinarian. While the Superior Court determined it did not, based on an analogous determination made by the Québec Court of Appeal in respect of pharmacists, this holding (and others) are now under appeal.[4]

In other fields, Canadian product liability class actions are local versions of earlier U.S. proceedings. Recent U.S. proceedings of interest include the following:

U.S. legal proceeding spotlight

EXCEDE® (ceftiofur crystalline free acid)	<p>In 2020, two separate actions were brought as a result of alleged severe adverse reactions to Zoetis' EXCEDE®.[5] <i>Knapp v. Zoetis</i> is a proposed class action proceeding brought in the Eastern District of Virginia based on an alleged severe anaphylaxis and permanent injury suffered by a horse. In <i>Foge, McKeever LCC et. al v. Zoetis</i>, the plaintiff alleges that a horse died shortly after being administered the defendant's drug. It is alleged that Zoetis knew and failed to warn veterinarian and animal owners of widespread adverse events as a result of the drug.</p> <p>EXCEDE® is an injectable antibiotic for lower streptococcal respiratory infection in horses approved and marketed in Canada.</p>
SYNOVEX® ONE GRASS (150 mg trenbolone acetate, 21 mg estradiol benzoate extended-release implants)	<p>In April 2021, an action in negligence was brought against Zoetis in North Dakota.[6] The plaintiffs allege that the medication caused the cattle to develop mature male features and engage in aggressive behaviour toward other cattle.</p> <p><i>Synovex® One Grass</i>, manufactured by Zoetis, is an implant for grazing cattle designed to improve performance in grazing cattle. A 150mg/21mg product is approved and marketed in Canada under the name Synovex® LA-G. Over fifteen class action lawsuits were initiated against Elanco Animal Health and Bayer in respect of SERESTO® (imidacloprid and flumethrin),[7] following media reports of severe adverse event, including <u>pet deaths</u>.</p> <p>SERESTO® does not appear to have been distributed by the manufacturer in Canada.</p>
SERESTO® (collar containing imidacloprid and flumethrin)	

This Update only provides general information and does not constitute legal or other professional advice. Specific advice should be sought in connection with your circumstances. For more information about the subject matter of this Update, please contact Vincent de Grandpré.

[1] Domestic Animals: Librela for dogs (Zoetis Canada Inc.), NexGard Combo for cats (Boehringer Ingelheim Animal Health Canada Inc.), Miratax for cats (Dechra Ltd), Bravecto One for dogs (Intervet Canada Corp.), Eradia for dogs (Virbac Animal Health Inc.), Coaschten for dogs (Dechra Ltd.), Amodip Flavoured Tablets for cats (Ceva Animal Health Inc.),

Comfortan for cats (Eurovet Animal Health Inc.); Farm Animals: Solofer for swine and piglets (Pharmacosmos A/S), Zeleris for cattle (Ceva Animal Health Inc.), Aservo Equihaler for horses (Boehringer Ingelheim Animal Health Canada Inc.), Gonabreed for cattle (Parnell Technologies PTY Ltd).

[2] From May 2018 to November 2019, there were nine NOC-NDS, as compared to twelve from November 2019 to June 2021.

[3] From May 2018 to November 2019, there were five NOC-NDS, as compared to eight from November 2019 to June 2021.

[4] Leave granted on February 12, 2021

[5] *Knapp v. Zoetis Inc.*, 3:20-CV-00191 Virginia Eastern District Court; *Foge, McKeever LLC et. al. v. Zoetis Inc.*, 2:2020-CV-01462 Pennsylvania Western District Court

[6] *Meidinger et. al. v. Zoetis, Inc.*, 3:21-CV-00097, North Dakota District Court

[7] *Bomwell v Bayer Healthcare LLC et al*, 2:21-cv-09479 (D.N.J.); *Borchek et al v Healthcare LLC et al*, 1:21-cv-2009 (N.D. Ill.); *Boulware-Jones v Bayer Corporation et al*, 2:21-cv-11114 (D.N.J.); *Czerniak v Bayer Healthcare LLC et al*, 9:21-cv-80689 (S.D. Fla.); *Dahlgren v Bayer Healthcare LLC et al*, 1:21-cv-03109 (S.D.N.Y.); *Dphrepaulezz v Bayer Healthcare LLC et al*, 1:21-cv-02439 (N.D. Cal.); *Gjelland v Elanco Animal Health, Inc*, 1:21-cv-01178 (S.D. Ind.); *Knudson v Bayer HealthCare LLC et al*, 6:21-cv-03108 (W.D. Mo.); *Levensten v Elanco Animal Health Incorporated et al*, 2:21-cv-02364 (D.C. E.Pa.); *Maiorino v Bayer Corporation et al*, 2:21-cv-07579 (D.N.J.); *McDermott et al v Elanco Animal Health, Inc et al*, 4:21-cv-00461 (E.D. Mo.); *Merriman v Bayer Healthcare LLC et al*, 1:21-cv-2227 (N.D. Cal.); *Revolinsky v Elanco Animal Health Incorporated et al*, 2:21-cv-10003 (D.N.J.); *Schneider v. Bayer Healthcare LLC et al*, 2:21-cv-02771 (C.D. Cal.); *Vargas et al v Elanco Animal Health Incorporated*, 2:21-cv-02506 (C.D. Cal.); *Walsh v Elanco Animal Health, Inc*, 1:21-cv-02929 (S.D.N.Y.)