Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

April 23, 2025

Senator Denise Tepler
Representative Victoria Doudera
Committee on Environment & Natural Resources
c/o Legislative Information Office
100 State House Station
Augusta, ME 04333

**Support LD 1423 – An Act to Improve Recycling by Updating the Stewardship Program for Packaging**

Dear Chairs Tepler, Doudera and Members of the Committee on Environment & Natural Resources,

Elanco Animal Health ("Elanco") thanks you for the opportunity to comment on LD 1423, legislation that would amend Maine's packaging stewardship statute. Elanco supports LD 1423 and the clarification the bill provides for animal health product manufacturers and the alignment the bill provides with other state packaging stewardship programs.

Elanco is a global leader in animal health dedicated to innovating and delivering products and services to prevent and treat disease in farm animals and pets, creating value for farmers, pet owners, veterinarians, stakeholders, and society as a whole. We manufacture and package these products at several global facilities, including in Winslow, Maine.

As outlined in the bill, animal drugs, biological products, parasiticides, medical devices and diagnostics used to treat, or administered to, animals and associated packaging are regulated by the U.S. Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. Sec. 301 et seq.), the U.S. Department of Agriculture (USDA) under the federal Virus-Serum-Toxin Act (VSTA) (21 U.S.C. Sec. 151 et seq.), and the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. Sec. 136 et seq.).

Each of these animal health products and their packaging are highly regulated by federal agencies. Our most critical objective is to provide a medicine that is safe and effective in packaging that protects the safety and integrity of the product and consumers. As an example, part of our submission for approval to the FDA includes approval for unique packaging designed to maintain stability of the product for the course of its intended shelf life to ensure safety and effectiveness for consumers.

Likewise, under the VSTA, the USDA regulates vaccines and biologics and diagnostic test kits. Under this regulatory framework, packaging must protect the integrity of a regulated product, including maintaining the appropriate temperature for a product. These are strict standards and there are limited options for meeting them. Additionally, packaging must meet labeling requirements.

Finally, under the FIFRA, the EPA regulates topically applied parasiticide products such as flea and tick preventatives. FIFRA §25(c)(3) authorizes EPA to establish packaging standards to protect public health and the environment, including appropriate packaging materials designed to protect children and adults from injury or illness resulting from accidental ingestion or contact with substances regulated under FIFRA.

Recognizing the rigorous regulatory framework and the impractical implications of packaging changes that would be in compliance with federal law, other states have exempted animal health products from such requirements. LD 1423 would update Maine's producer responsibility law and align it with the programs now established in other states. We urge the committee to pass LD 1423.

Thank you,

John Stewart
Senior Director, Government Affairs
Elanco Animal Health