Product Quality & Safety Issue Brief

Importance to Elanco and our Stakeholders

With nearly 70 years of history in the animal health business, we're committed to helping our customers improve the health of animals in their care. We have a diverse portfolio of products for both pets and farm animals, marketed under approximately 200 brands.

Delivering safe, quality and reliable products is critical to fulfilling our customer promise and maintaining our reputation of trust around the world.

Our Action

Our Manufacturing and Quality (M&Q) organization focuses on delivering an uninterrupted supply of products – prioritizing quality and safety, while maintaining competitive costs. Our Pharmacovigilance organization, part of our Research and Development organization, constantly monitors data for safety signals related to products on the market.

We maintain controls and processes to ensure our products are safe, efficacious and reliably meet the quality specifications necessary for their intended use – in line with requirements for each product's respective Marketing Authorization.

We collaborate closely with regulatory authorities in countries where our products are marketed to ensure compliant registration – including, but not limited to:

- Center for Veterinary Medicine (CVM), part of the U.S. Food and Drug Administration (FDA)
- U.S. Environmental Protection Agency (EPA)
- Center for Veterinary Biologics (CVB), part of the U.S. Department of Agriculture (USDA)
- European Medicines Agency (EMA)
- Japanese Ministry of Agriculture, Forestry and Fisheries (JMAFF)
- Brazilian Ministry of Agriculture, Livestock and Food Supply (MAPA)
- Chinese Institute of Veterinary Drug Control (IVDC) at the Ministry of Agriculture and Rural Affairs (MARA)

We apply robust quality standards at every stage of research, development, manufacturing and distribution – governed by our global Quality Management System. Our Standard Operating Procedures (SOPs) ensure every Elanco product is developed, produced and distributed in

compliance with applicable quality requirements. These SOPs are reviewed and updated regularly.

Our Global Quality Assurance team (part of our M&Q organization) regularly assesses and audits our manufacturing network as well as contract manufacturing partners to ensure adherence to all applicable requirements. Before release to market, every product batch from our manufacturing and contract manufacturing sites is tested for compliance with specifications in the product dossier – to confirm the requirements of the marketing authorization and ensure adequate safety, quality and efficacy. Additionally, we perform product stability testing to ensure the safety, quality and efficacy of our products over the course of their approved shelf life.

We determine, evaluate and record potential quality defects identified in batch testing and, in response, take necessary action to mitigate identified defects in consultation with local regulatory authorities. Our quality assurance SOPs require detailed root cause analysis of any identified quality defect and ensure that processes are updated to reflect findings and mitigate potential recurrence.

Additionally, we cooperate with inquiries by applicable regulatory authorities and, when requested, make our manufacturing facilities, distribution facilities and pharmacovigilance system and data available for inspection and review.

Internally, we evaluate feedback provided by regulatory authorities and maintain or adjust our facilities and processes, as appropriate.

Pharmacovigilance

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.

Our Pharmacovigilance team monitors safety information from solicited and unsolicited sources (such as clinical trials or individual adverse event reports from animal owners) for validated safety signals. If a valid signal is identified, Elanco and the appropriate regulatory agency will decide the best approach – which can include updating product label language or providing timely information about the safety of medications to regulatory agencies, animal owners and prescribing veterinarians.

Potential Defects

We have strong globally managed and coordinated quality control and quality assurance programs in place at all internal manufacturing sites and external manufacturing hubs. We regularly inspect and audit our internal sites and third-party manufacturing locations and record any potential quality defects associated with our products.

Should we ever identify a quality concern, we would promptly take all necessary action to protect the supply chain in cooperation with local regulatory authorities. Our quality assurance process mandates root cause analysis and evaluation for all incidents – ensuring appropriate mitigating, corrective and preventative actions are implemented accordingly.

Product Returns

Customers in the U.S.

In the U.S., our commercial policies allow for the return of products if certain criteria are met, as outlined in our Return Policy in our Terms and Conditions and in our commercial contracts. We investigate reasons for returns and distinguish three types of returns: Unusable, Return to Stock or Destroyed in Field.

When a product is returned and received at designated facilities, SOPs describe how Elanco products returned to an Elanco warehouse or third-party partners such as logistics service providers should be handled. The SOPs also outline the rules for further disposition of returned products. Our Health, Safety and Environmental (HSE) organization maintains additional SOPs detailing appropriate processes for the management and disposal of both waste and hazardous waste material.

In rare instances, we evaluate a product for reintegration into the supply chain. In such circumstances, our U.S. Affiliate Quality (USAQ) team applies a standard process for assessing the product's suitability. This is necessary to ensure that only product fit for use is considered for re-integration into saleable stock. For products destroyed in the field, we advise our customers to comply with guidelines for appropriate disposal, per the product information documents.

Customers Outside the U.S.

For markets outside of the U.S., our regional affiliates have local commercial policies which are based on our Commercial Policy Blueprint for Elanco International. This blueprint identifies applicable global SOPs and return procedures. The return processes defined in affiliates' commercial policies include a local business review, approval process and requirements for the creation and retention of appropriate supporting documentation aligned with applicable local regulations and global procedures.

Inquiries or Concerns

Inquiries about Elanco products may be directed to the Elanco Animal Health Technical Support Center at 1-888-545-5973.

If you are aware of an adverse experience involving an Elanco product potentially including a known or suspected human death, please call the U.S. Elanco phone line at +1-888-545-5973 or +1-800-428-4441 immediately. For other location information, click here or refer to the product label for instructions.

To report a complaint about an Elanco product, please call the Elanco phone line at +1-888-545-5973 or +1-800-428-4441

Governance and Risk Management

Our M&Q organization is led by our Executive Vice President of Manufacturing and Quality. Our Global Quality Assurance team (part of our M&Q organization) regularly assesses and audits our manufacturing network.

Our Pharmacovigilance organization is led by our Executive Vice President of Innovation and Regulatory Affairs.

The Elanco Manufacturing Policy lead team, the Elanco Executive Committee (which includes our Chief Executive Officer and direct reports) as well as the Audit Committee of the Board of Directors are briefed regularly on topics related to product quality and safety.

The content of this brief is informed by the following ESG disclosure standards:

- *Policies and commitments that guide Elanco's approach to the material issue (GRI Disclosure 3-3c)*
- *Mechanisms to integrate the material issue into strategy, decision-making and financial planning (IFRS S1 General Requirements Standard)*
- *Actions taken to respond to the material issue, with a qualitative assessment of how these actions support the 'resilience' of Elanco (IFRS S1 General Requirements Standard)*
- *Action taken to manage impacts related to the issue (GRI Disclosure 3-3d)*
- *Processes used to track effectiveness and lessons learned (GRI Disclosure 3-3e)*
- *Board and management responsibilities related to the material issue (IFRS S1 General Requirements Standard, GRI 2-12, 2-13, 2-14)*