Dear Veterinarian and Animal Healthcare Professional,

Elanco, in agreement with the European Medicines Agency (EMA) and <National Competent Authority>, would like to inform you of the following:

Summary

• The marketing authorisation of Kexxtone has been suspended due to a quality defect which has resulted in cases where cattle regurgitated the device while it still contained monensin tablets. This resulted in increased accidental exposure, including deaths, in non-target species (dogs) and potential lack of efficacy in cattle.

• Kexxtone 32.4 g continuous-release intraruminal device for cattle has now been suspended from the EU market until Elanco implements corrective and preventive actions to address this quality defect.

• To minimise the risk of exposure to non-target species, all batches of Kexxtone will be recalled from the market. This recall will begin on dd mmm 2024 to allow for manufacturing changes and additional quality control testing to be implemented.

• Animal Healthcare Professionals should no longer use Kexxtone and consider other appropriate alternatives.

Background information

Kexxtone 32.4 g continuous-release intraruminal device for cattle is a veterinary medicinal product (VMP) containing the active substance monensin. It was authorised in 2013 and is intended for the reduction in the incidence of ketosis in the peri-parturient dairy cow/heifer which is expected to develop ketosis.

Kexxtone is a controlled-release formulation of monensin sodium in tablet form which is enclosed in a polypropylene delivery device. The device is intended to be retained in the rumen for at least the duration of the approximately 95-day payout period.

Due to a change in manufacturing process, a quality defect arose that led to an increase in regurgitation of boluses by cattle that still contained monensin tablets. This led to concerns over lack of efficacy in cattle and increased risk of accidental exposure to regurgitated Kexxtone devices by non-target species, with a corresponding link to death in dogs. Following assessment of all available data related to this quality defect, EMA’s Committee for Veterinary Medicinal Products (CVMP) recommended the suspension of the marketing authorisation for Kexxtone (EU/2/12/145/001-003) until enhanced manufacturing control testing can be identified to confirm the release rate and minimise the risk of accidental exposure in non-target species from a regurgitated bolus.

To prevent accidental exposure and minimise the risk of adverse events in non-target species, all batches of Kexxtone are being recalled from the market to veterinarian level as a precautionary
measure.

The market recall relates to the following batches of Kexxtone:

<table>
<thead>
<tr>
<th>Country</th>
<th>Batch number</th>
<th>Expiration date</th>
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<tbody>
<tr>
<td>{to be completed nationally}</td>
<td>{to be completed nationally}</td>
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Elanco is currently working in close collaboration with the European Medicines Agency. Elanco is committed to resolving this concern to get Kexxtone back on the market given the importance of this tool to farmers and to the health and well-being of cattle.

**Call for reporting**

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product.

If farmers notice any side effects, even those already listed in the package leaflet for Kexxtone, or think that the medicine has not worked, please advise them to contact, in the first instance, their veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of the package leaflet, or via your national reporting system: {national system details}.

The information provided should contain at minimum the product identification number (visible on barrel) and administration date to the animal.

**Company contact point**

Should you have any questions or require additional information, please contact Elanco at: {to be completed nationally}
<table>
<thead>
<tr>
<th>TOPIC-SPECIFIC COMMUNICATION PLAN FOR:</th>
<th>Direct animal health care professional communication (DaHPC) on Kexxtone batch recall</th>
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<tbody>
<tr>
<td>Medicinal product(s)/active substance(s)</td>
<td>Kexxtone (monensin)</td>
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</table>
| Marketing authorisation holder(s) | Elanco GmbH  
Heinz-Lohmann-Str. 4  
27472 Cuxhaven  
Germany |
| Issue and objectives of the communication | Marketing authorisation suspension and market batch recall for the product, due to concern of incomplete payout, resultant lack of efficacy, and increased risk to non-target species due to accidental exposure to regurgitated boluses of Kexxtone. |
| Target audience: direct animal health care professional communication | Veterinarians, wholesalers, local distributors, and pharmacies that have received the product.  
Details for each country to be discussed and agreed with the National Competent Authorities (NCAs) of the countries where Kexxtone is marketed. |
| Member States where the communication will be distributed | The communication will be disseminated in the European Economic Area (EEA) countries where Kexxtone is marketed. |
| Stakeholders to coordinate with | • European Medicines Agency (EMA)  
• National competent authorities of the EEA countries where Kexxtone is marketed  
• Veterinary associations in the EEA countries where Kexxtone is marketed (if applicable). |
| Means of dissemination | • Email  
• Post (via courier)  
• Publication on the MAH website (if applicable)  
• Publication on the EMA website  
• Publication on the websites of the national competent authorities of the countries where Kexxtone is marketed (where applicable). |
| Follow-up and measurement of effectiveness | • Acknowledgement of receipt from veterinarians, in accordance with each concerned Member State (MS) national policy on batch recall, will be collated by local PV and evaluated. The Agency will then be informed of the evaluation in due course.  
• Feedback from veterinarians: comments, questions, etc.  
• Need and content of follow-up communication to |
be considered nationally, in accordance with each Member States legislation and specific requirements.