Training Seminar for OIE Focal Points for Veterinary Products, 6ème cycle

Kuala Lumpur, Malaysia, 14 – 16 January 2020

Working Group Session: Substandard and falsified veterinary products

Country name: .....

1. a) Is there any surveillance system or network (formal or informal) in your country to detect and follow up when there is something wrong with the quality of a veterinary product?

   ☐ Yes ☐ No

   If yes, please provide details, even if this is an informal network.

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   b) Who is the main or first point of contact/authority to manage the situation (within a short time frame)?

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2. a) If you were given information of a veterinary product that **did not have the expected effect**, would you (or another colleague, or the relevant Department in your country), with the resources currently available to you, be able to differentiate between:

   - a substandard veterinary product;
   - a falsified veterinary product; and
   - a side effect (adverse drug reaction) to a good quality product?

   ☐ Yes ☐ No

   If yes, then how?

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   b) What would you do, and who would you contact, if you knew the product was:

   I. A substandard veterinary product?

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   II. A falsified veterinary product?

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   III. A side effect (adverse drug reaction) to a good quality product?

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3. Please find on the next page an example notification sheet. Would it be feasible for you to take appropriate action within your responsibilities via your network?

☐ Yes ☐ No

How?

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Veterinary Medicines Regulatory Authority

Rapid Alert Notification Reference number: F5-07-2019

Product: Veterinary medicinal product	**Marketing Authorisation Number:** 0000XYZ
Brand name: Amoxilot	**Generic name:** Amoxicillin
Batch number: 047438E	**Expiry date:** 06/2022
Marketing Authorisation Holder: Pharmavet	**Manufacturer(s):** Pharmavet

Details of incident:

On 2nd June, a batch of 'Amoxilot' was reported to the local medicines authority after a number of clients complained to their veterinarians about a lack of efficacy. It was subsequently confirmed by the manufacturer on the 12th June that that this product had a batch number that did not correspond to any existing batch numbers. Upon further testing, five products with this batch number were found to contain no amoxicillin.

Action taken:

A recall to veterinary level is planned. Veterinarians and consumers should be informed of the products in question so that the affected products and batches can be recalled.

Additional questions (time permitting)

4. Does your country have a formalised surveillance programme for veterinary product quality which involves routinely taking samples from the market for laboratory testing?

☐ Yes ☐ No

If you have this information, approximately how many veterinary products do you analyse each year? Approximately what percentage are found to be non-compliant?

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5. Does your country have a national or regional laboratory for controlling and monitoring the quality of VMPs?

☐ Yes ☐ No

If yes, for which products? (Drugs/pharmaceuticals? Vaccines?) If no, do you have access to another laboratory which can provide testing?

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6. Is there a regularly updated database of veterinary products authorised in your country, including imported veterinary products, with their detailed composition?

☐ Yes ☐ No

7. Do you have a legal basis to take samples on the market?

☐ Yes ☐ No

8. Do you have a legal basis to order recall of a batch of VMPS that is not in compliance with the marketing authorisation?

☐ Yes ☐ No