Elisabeth Erlacher-Vindel (Head)
Rebecca Hibbard (Intern and future staff member)
Antimicrobial Resistance and Veterinary Products Department

Substandard and Falsified Veterinary Medical Products

Addis Ababa – Debre-Zeit (Ethiopia) 9-11 July 2019

Why should we care?

Untreated illness (or preventable illness)

Poisonings

Loss of faith in medical institutions when medicines don't work

Contribution to the development of antimicrobial resistance

Interest in the topic from an AMR perspective

WHO Global Action Plan on Antimicrobial Resistance (2015)

Objective 4: Optimize the use of antimicrobial medicines in human and animal health.

"Related weaknesses that contribute to development of antimicrobial resistance include … the prevalence of substandard medicines for both human and veterinary use."

OIE 2nd Global Conference on AMR and Prudent Use of Antimicrobial Agents (2018)

Recommendation 6: "Explore the possibility of building an information system of falsified and substandard drugs in the animal sectors illegally circulating within and between countries and building on the experience of the monitoring systems set up by WHO for drugs designated for human use taking a "One Health" approach."

Objectives of the internship

1. Provide an overview of the current situation concerning substandard and falsified veterinary medical products, and their surveillance
2. Undertake an evaluation of the WHO's Global Surveillance and Monitoring System for Substandard and Falsified Medical Products.
3. Develop a model for an OIE global surveillance system for substandard and falsified veterinary medical products

How big is the problem?

Medical products for veterinary use

Prevalence studies – only 10 studies across 20 years, all in Africa

Antibiotics: 11%-93% (4 studies)

Anthelmintics: 22%-58% (4 studies)

Trypanocides 28%-100% (8 studies)

Regulated and non-regulated

HealthforAnimals conducted a qualitative analysis

- Compounded veterinary medicines in North America
- Parallel trade in Europe

Why prevalence is difficult to estimate

Representativeness

Sample size

Changes over time means that data is rapidly invalid

Potential for an OIE global surveillance system for substandard and falsified veterinary medical products

Preliminary steps

Collect information from Member Countries:

- Expectations for a surveillance system
- Systems already in place for surveillance and control of SF VMPs
- Barriers to implementation of surveillance

Information sourced from:

- Focal Point training seminars
- PVS
- Questionnaire

Framework of surveillance

Use the same basic framework as the WHO

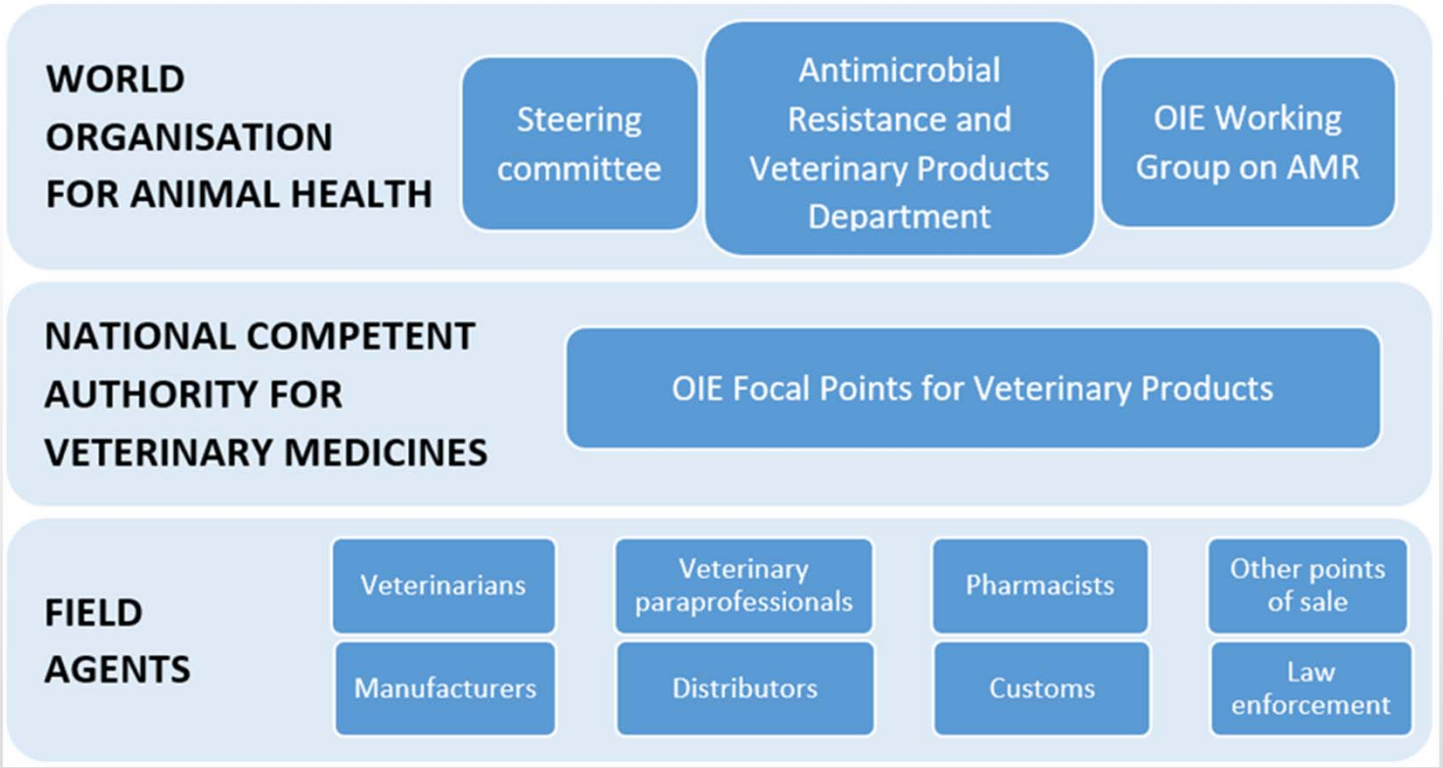
- **Subjects of surveillance:** Substandard and falsified veterinary medical products
- **Epidemiological unit:** Incident (the discovery of substandard of falsified veterinary medical products at one time and place)
- **Population under surveillance:** Aim to be exhaustive in all OIE Member Countries
- Surveillance would not actually be conducted by the OIE – **data** would be **collected from surveillance at a national level**
- OIE could provide **guidelines for development of a surveillance protocol**, and provide assistance to Member Countries in meeting these guidelines

Case definition

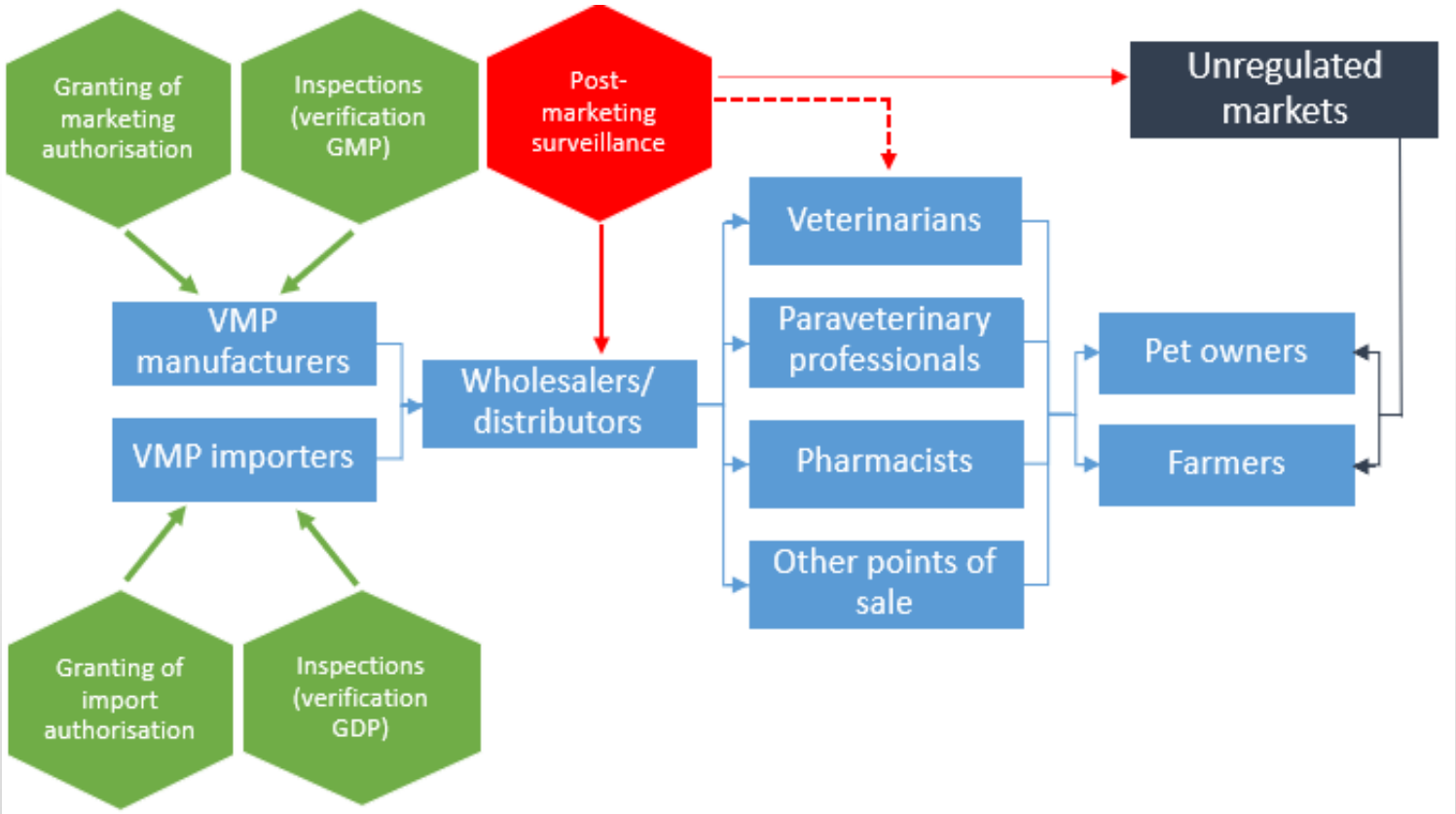
Adapted from WHO case definitions

Type of case	Criteria to meet to the case definition
Confirmed SF VMP	Verification by the following parties: • The stated manufacturer, or the manufacturing authorisation holder, that the product does not correspond to the stated manufacturer's records. • Confirmation that the product does not meet specifications by a laboratory certified by the OIE for quality testing of VMPs.
Probable SF VMP	• The product has failed field screening examination, and/or • The product has failed local laboratory testing, and/or • Photographic evidence suggests the product is SF.
Suspect SF VMP	A product notified to the system, for which: • The OIE does not have information which allows the case to satisfy the criteria of confirmed or probable, and/or • Available information is deemed unreliable.

Institutional organisation



Method of surveillance



Laboratories

- Build regional capacity through developing regional centres ?
- Twinning projects ?
- Designation of specific laboratories?
- Link to Collaborating Centers?

Data management

Data collection

- Notifications made by Focal Points via online form
- Data collected from (sub)regional authorities
- Notifications from other actors on informal basis

Data processing

- Data processed as it comes in, response within 48 hours of receipt
- Manual data verification and validation – important for standardisation

Data analysis

- Identify patterns in distribution of reported incidents
- Consider alongside AMU data

Communication

Sharing of reported data	Surveillance system info	raise awareness
• Notification of confirmed incidents sent to Focal Points	• Internal bulletin at regional level • Annual report	• Work in conjunction with other partners

Training

- Integrate with Focal Point Training seminars
- Cascade training (“Train the Trainers”)

Thank you for your attention

further discussion in Working Groups