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Substandard and Falsified Veterinary Products

Kuala Lumpur, 14-16 January 2020

Outline of presentation

- Introduction to substandard and falsified veterinary products
- Surveillance of substandard and falsified veterinary products
- Potential for a global surveillance system of substandard and falsified veterinary products

1. Introduction to substandard and falsified veterinary products

What are substandard and falsified veterinary products?

Falsified veterinary products

Veterinary products that **deliberately/fraudulently misrepresent** their identity, composition, or source.

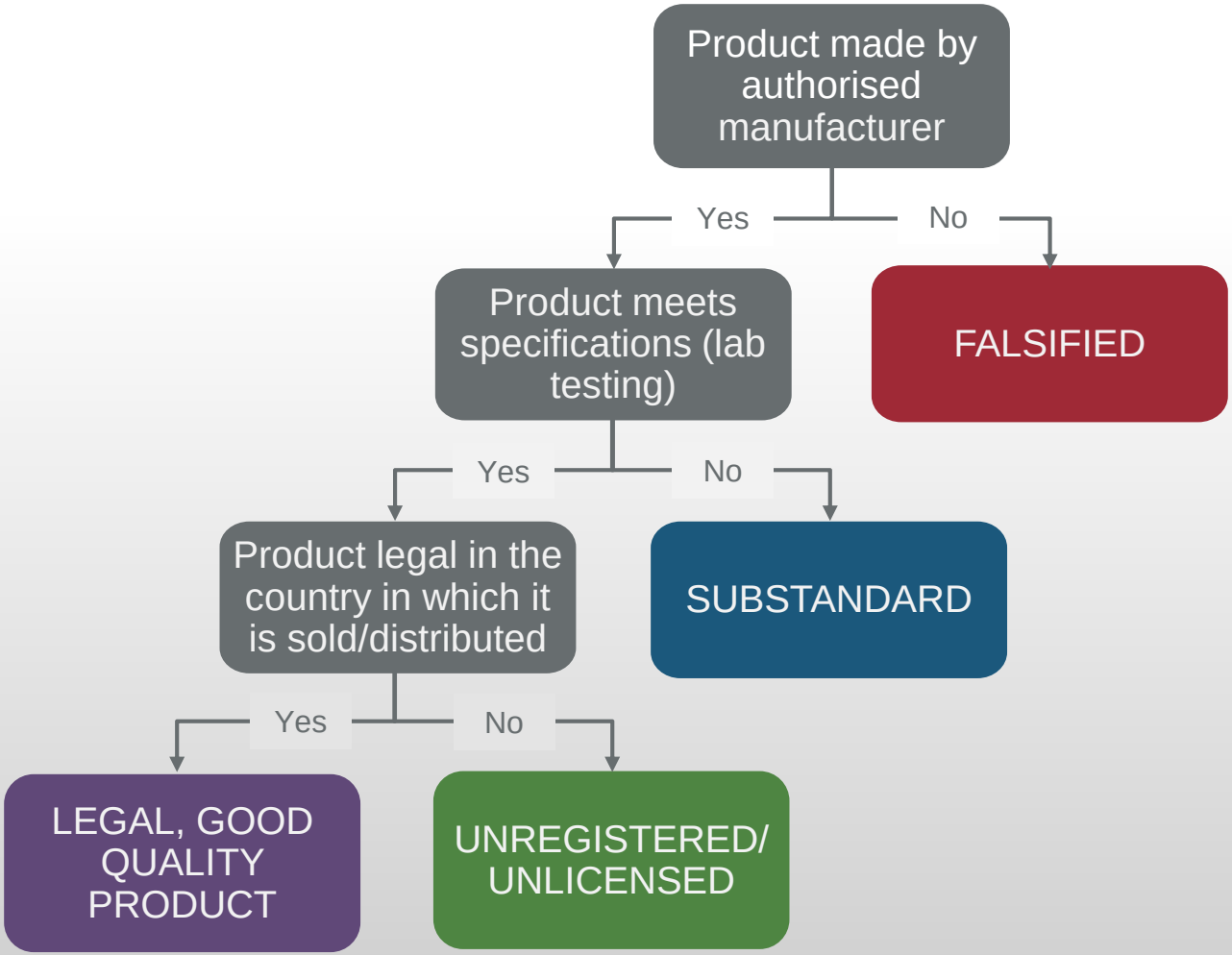
Substandard veterinary products

Authorised veterinary products that **fail to meet either their quality standards, or their specifications**, or both.

Unregistered/unlicensed veterinary products

Veterinary products that **have not undergone evaluation and/or approval** by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

What are substandard and falsified veterinary products?



How big is the problem?

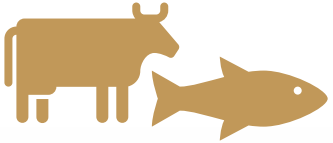
- From the literature – studies testing veterinary product quality

Antibiotics
11-95% of samples non-compliant
9 studies

Anthelmintics
22-58% of samples non-compliant
4 studies

Trypanocides
28-100% of samples non-compliant
7 studies

Regulated and unregulated markets



Products for terrestrial and aquatic animals

However…
- Small sample sizes – difficult to extrapolate data
- Selected geographical locations – anecdotal evidence suggests problem is global

What causes the problem?

- HealthforAnimals – qualitative analysis found that illegal veterinary products are associated with:

Limited legal access to authentic veterinary products

Less well developed regulatory systems and enforcement

- Consistent with findings of primary drivers for SF medical products for human use by WHO:

Weak technical capacity to ensure good practice

Constrained access to affordable, quality, safe and effective medical products

Low standards of governance

Potential consequences

Untreated illness (or preventable illness)

Poisonings

Loss of faith in veterinarians when treatments don’t work

Contribution to the development of antimicrobial resistance

Interest in the topic from an AMR perspective

Global Action Plan on Antimicrobial Resistance (2015)

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

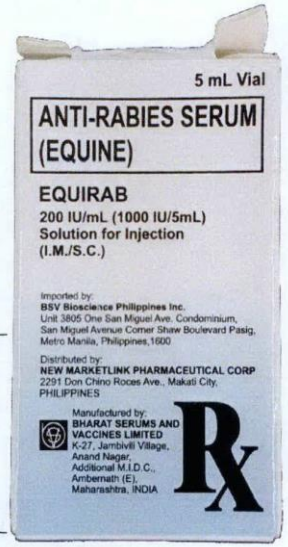
"Related weaknesses that contribute to development of antimicrobial resistance include ... the prevalence of substandard medicines for both human and veterinary use."

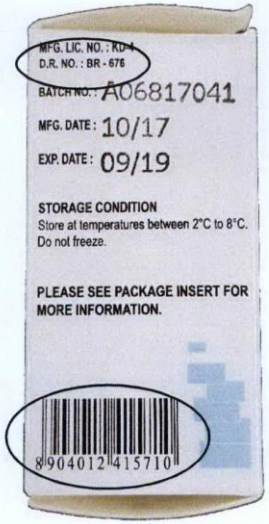
2nd OIE Global Conference on AMR and Prudent Use of Antimicrobial Agents (2018)

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."

Example of a falsified veterinary product

Authentic product





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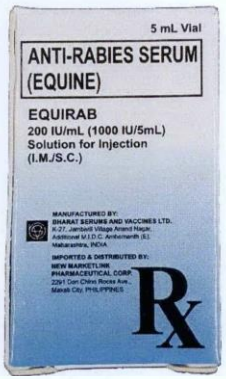
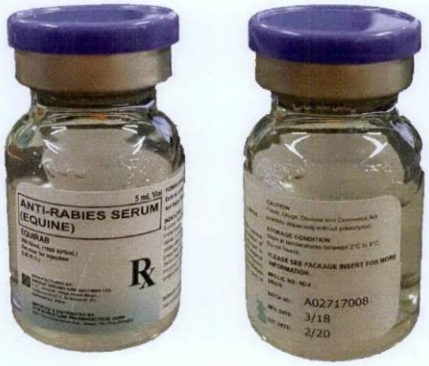
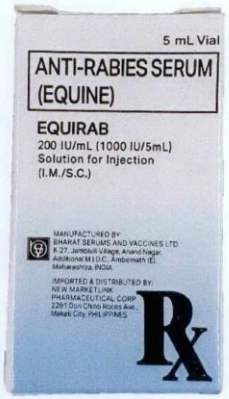
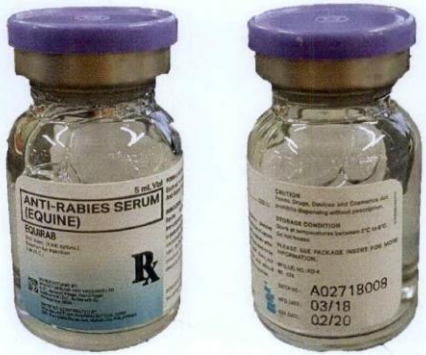
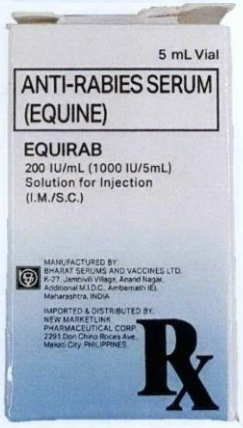










2. Surveillance of substandard and falsified veterinary products

Passive surveillance at a national or regional level

Notification to the authority responsible for veterinary products by:

Health professionals: veterinarians, veterinary paraprofessionals, pharmacists

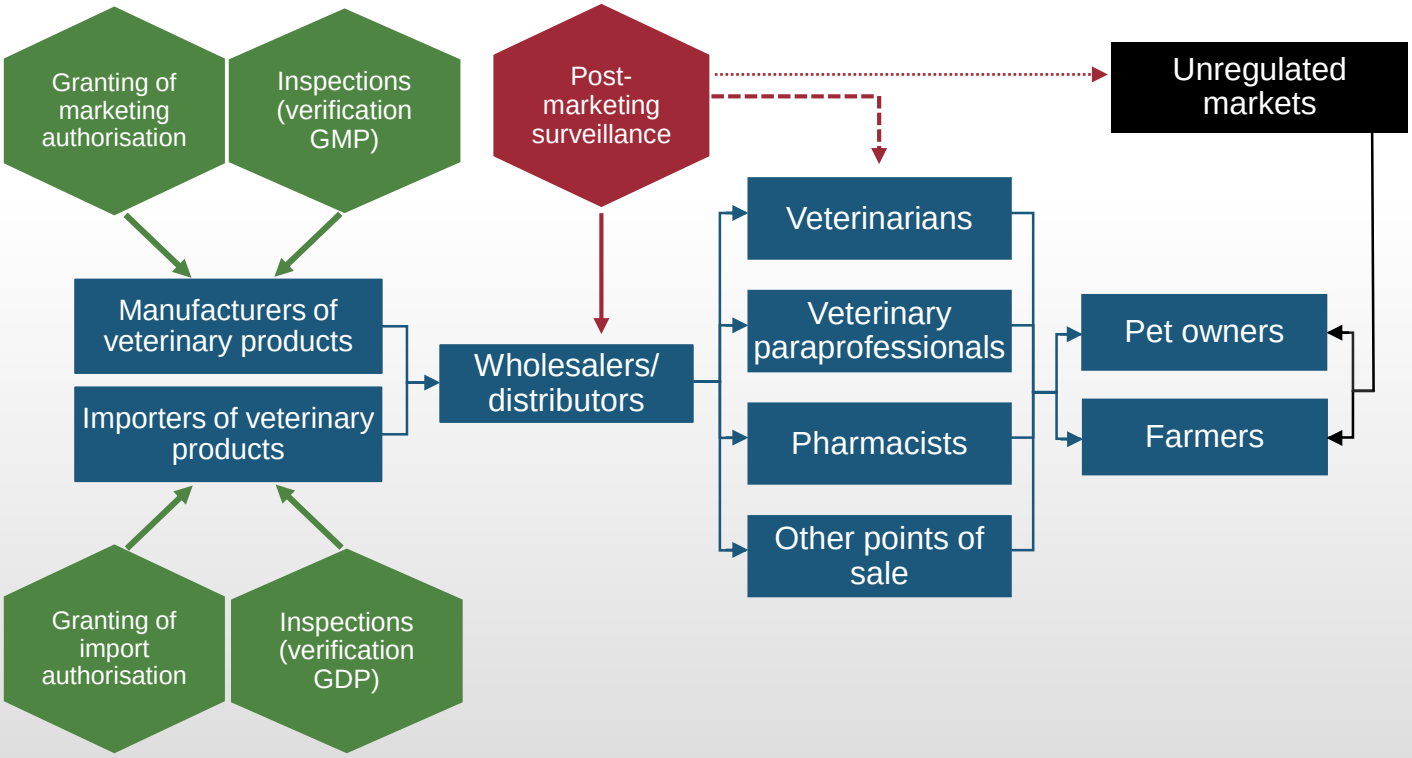
Supply chain: Wholesalers and distributors

Pharmaceutical industry: Manufacturers and marketing authorisation holders

Law enforcement authorities: Customs and police

The general public: Animal owners, including farmers and pet owners

Active surveillance at a national or regional level



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

Why a global system?

- Information collected can be used to improve access to good quality veterinary products
- WHO's surveillance system provides an example of how this can be done

The WHO's Global Monitoring and Surveillance System for Substandard and Falsified Medical Products (GSMS)

GSMS is coordinated at WHO Headquarters by the Substandard and Falsified Medical Products Group

Network of Focal Points working for national and regional Medicine Regulatory Authorities (MRAs)

Focal Points notify incidents of suspect SF medical products to the WHO, which are automatically included in the database

The WHO provides a response within 24-48 hours, provides technical support and issues alerts

The WHO's Global Monitoring and Surveillance System for Substandard and Falsified Medical Products (GSMS)

Results from the first 4 years (2013-2017)

- Cases reported:

111 countries have reported incidents

2000+ reports of suspect products

Majority concern anti-infectives and antiparasitics

- WHO has provided:

Technical assistance in 100+ cases

26 global drug alerts, in addition to local warnings and regional bulletins

How could an OIE system function?

- Use the same basic framework as the WHO
- Surveillance would not actually be conducted by the OIE – data would be **collected from surveillance at a national or regional level**
- OIE could develop **guidelines for development of a surveillance protocol**, and provide assistance to Member Countries in meeting these guidelines

Organisational Structure (Draft)

WORLD ORGANISATION FOR ANIMAL HEALTH (OIE)

- Antimicrobial Resistance and Veterinary Products Department

NATIONAL AUTHORITY FOR VETERINARY PRODUCTS

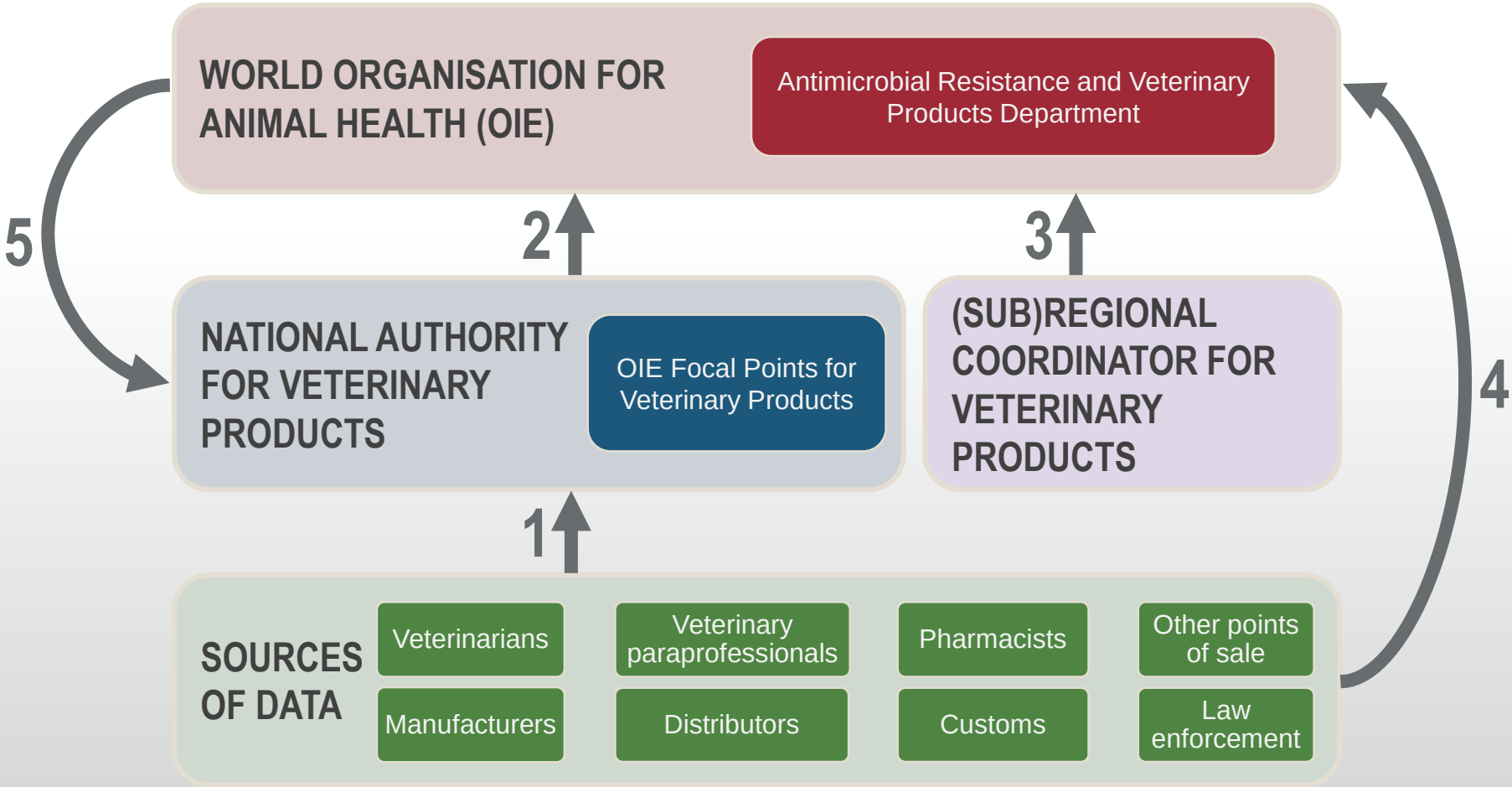
- OIE Focal Points for Veterinary Products

(SUB)REGIONAL COORDINATOR FOR VETERINARY PRODUCTS

SOURCES OF DATA

- Veterinarians
- Veterinary paraprofessionals
- Pharmacists
- Other points of sale
- Manufacturers
- Distributors
- Customs
- Law enforcement

Flow of Information (Draft)



Data management

Data collection

Focal Points notifications

Regional coordinators

Other institutions/ individuals

Data processing

Data processed within 48 hours

Validation of data by OIE, including follow up with Focal Points

Data analysis

Identify patterns of incidents

Consider alongside AMU data

Better understand the global picture

Data dissemination

- Return of information to Member Countries

Alert system for high risk incidents

Annual reports

Eventually, a searchable database

Regional information

- Awareness raising

Work with other partners

Provide material for Member Country use

Preliminary steps

- Collect feedback from OIE Member Countries

Expectations for a surveillance system

Systems already in place for surveillance and control of veterinary product quality

Relevant contact points for veterinary product quality

Barriers to implementing a surveillance system

→ Tomorrow's working group session

Thank you for your attention

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