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?

- Product made by authorised manufacturer
  - Yes
    - Product meets specifications (lab testing)
      - Yes
        - Product legal in the country in which it is sold/distributed
          - Yes: LEGAL, GOOD QUALITY PRODUCT
          - No: UNREGISTERED/UNLICENSED
      - No: FALSIFIED
  - No: SUBSTANDARD
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
  
  However…
  - Small sample sizes – difficult to extrapolate data
  - Selected geographical locations – anecdotal evidence suggests problem is global

- Regulated and unregulated markets
- Products for terrestrial and aquatic animals
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


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
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

- Wholesalers/distributors
- Manufacturers of veterinary products
- Importers of veterinary products
- Veterinarians
- Veterinary paraprofessionals
- Pharmacists
- Other points of sale
- Pet owners
- Farmers
- Unregulated markets
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)

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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
  - Eventually, a searchable database
  - Annual reports
  - 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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