Rebecca Hibbard
Chargée de mission, Antimicrobial Resistance and Veterinary Products Department

Substandard and falsified veterinary products

Focal Point Webinar for the Middle East
8th December 2020
Outline

1. Introduction to substandard and falsified veterinary products
2. Current situation of substandard and falsified veterinary products
3. Potential for a global surveillance system of substandard and falsified veterinary products
1. Introduction to substandard and falsified veterinary products
What type of veterinary products are we talking about?

- Substandard
- Falsified
- Unregistered/unlicensed
What type of veterinary products are we talking about?

- 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
The importance of veterinary product quality

Potential consequences include:

- Untreated illness (or preventable illness)
- Poisonings
- Loss of faith in veterinarians when treatments don’t work
- Contribution to the development of antimicrobial resistance
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."

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."
Current situation of substandard and falsified veterinary products
How big is the problem of SF veterinary products?

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

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

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

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
HealthforAnimals: Qualitative analysis found illegal veterinary products are associated with:

- Limited legal access to authentic veterinary products
- Less well-developed regulatory systems and enforcement

Consistent with WHO findings of primary drivers for SF medical products (for human use):

- Constrained access to affordable, quality, safe and effective medical products
- Low standards of governance
- Weak technical capacity to ensure good practice
Example of a falsified veterinary product

**Authentic product**

Very light blue

**Falsified product**
Surveillance of substandard and falsified veterinary products
Passive surveillance at a national or regional level

Notification to the authority responsible for veterinary products by:

**Veterinary professionals:** Veterinarians, veterinary paraprofessionals, pharmacists

**Supply chain:** Wholesalers and distributors

**Pharmaceutical industry:** Manufacturers and marketing authorisation holders

**Law enforcement:** Customs and the police

**The general public:** Animal owners
Active surveillance at a national or regional level

- Manufacturers of veterinary products
- Importers of veterinary products
- Inspections (verification GMP)
- Post-marketing surveillance
- Inspections (verification GDP)
- Granting of marketing authorisation
- Granting of import authorisation
- Wholesalers/distributors
- Veterinarians
- Veterinary paraprofessionals
- Pharmacists
- Pet owners
- Farmers
- Other points of sale
- Unregulated markets
- Pet owners
- Farmers
- Other points of sale
- Unregulated markets
Potential for a global surveillance system of substandard and falsified veterinary products
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 (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
- 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
WHO 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’s Global Monitoring and Surveillance System for substandard and falsified medical products
  - Coordinated at Headquarters level
  - Operate through a network of Focal Points

- 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
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
- Alerts (for high risk incidents)
- Annual reports
- Eventually, a searchable database
Collect feedback from OIE Member Countries – today’s discussion!

**Preliminary steps**

- **Expectations for a surveillance system**
  - Would this system be useful for your country?

- **Systems already in place for surveillance**
  - Does your country already conduct some surveillance?

- **Relevant contact points for veterinary product quality**
  - If not the Focal Point, then who?

- **Barriers to implementing surveillance**
  - What will be the challenges?

In the future, can start to pilot different parts of this system
### Preliminary steps

#### Draft questionnaire for discussion and future piloting

**Immediate notification form**

<table>
<thead>
<tr>
<th>OIE Immediate Notification Form for Substandard and Falsified Veterinary Products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Reporting Agent</strong></td>
</tr>
<tr>
<td>1. <strong>Title</strong></td>
</tr>
<tr>
<td>2. <strong>Name (First name, SURNAME)</strong></td>
</tr>
<tr>
<td>3. <strong>Role with respect to the OIE</strong></td>
</tr>
<tr>
<td>4. <strong>Organisation</strong></td>
</tr>
<tr>
<td>5. <strong>Organisation’s Address</strong></td>
</tr>
<tr>
<td>6. <strong>Country</strong></td>
</tr>
<tr>
<td>7. <strong>Phone Number</strong></td>
</tr>
<tr>
<td>8. <strong>Email Address</strong></td>
</tr>
<tr>
<td>9. <strong>Is this report related to an incident you have previously reported to the OIE?</strong></td>
</tr>
<tr>
<td>10. <strong>Are you willing for the information in this report to be shared with other OIE focal points for veterinary products?</strong></td>
</tr>
</tbody>
</table>

**B. Details of Suspect Veterinary Product (Product 1)**

**Questions 11 to 27 relate to the details of the veterinary medical product which was discovered for this incident, and any analysis that may have been done for this product. Please enter all details as they are presented on the packaging of the suspect product, even if this is known to be false. If the product was produced with no packaging, please respond with “no packaging.”** For questions 9-17 and move directly to section C.

<table>
<thead>
<tr>
<th>5</th>
<th>Name of suspect product (brand name)</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>Active ingredient(s) (generic name) and strength</td>
</tr>
<tr>
<td>17</td>
<td>Packaging form</td>
</tr>
<tr>
<td>18</td>
<td>Method of administration</td>
</tr>
<tr>
<td>19</td>
<td>Manufacturer</td>
</tr>
</tbody>
</table>

### Ongoing reporting form

**OIE Reporting Form for Information on Substandard and Falsified Veterinary Products**

Please provide as much detail as you can. If you do not have all the information requested on the form, please fill in the information that you do have. Follow up information can be sent through email.

**A. Reporting Agent**

| 1 | Title |
| 2 | Name (First name, SURNAME) |
| 3 | Role with respect to the OIE |
| 4 | Organisation |
| 5 | Organisation’s Address |
| 6 | Country |
| 7 | Phone Number |
| 8 | Email Address |

**B. Information on incidents of substandard and falsified veterinary products**

- **Were there any incidents of suspected or confirmed substandard or falsified veterinary products found in your country this year?**
  - [ ] Yes, and the incident(s) have been notified to the OIE
  - [ ] Yes, but the incident(s) have not yet been notified to the OIE
  - [ ] No incidents of substandard or falsified veterinary products were found

- **If you answered yes to question 9, but have not yet provided those details to the OIE, please let us know any barriers to reporting this incident that you found.**
  - [ ] Other

- **Did you cooperate with any other countries in managing a suspected substandard or falsified veterinary product this year?**
  - [ ] Yes
  - [ ] No

- **Is there a competent authority (government department or other institution) who is responsible for registration and authorisation of veterinary products in your country?**
  - [ ] Yes
  - [ ] No

  If yes, please indicate the name: [ ]

---

23
Five key activities identified for the project proposal

- Training Seminars for OIE National Focal Points for Veterinary Products
- Development of a global information and alert system for SF veterinary products
- Development of guidelines on post-marketing surveillance of veterinary product quality
- Explore options for regional testing of veterinary product quality
- Explore options for strengthening surveillance at field level
Rebecca Hibbard
Chargée de mission

Quality of veterinary products

Focal Point Webinar for the Middle East
8th December 2020