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Substandard and falsified veterinary products

Focal Point Webinar for the Middle East
8th December 2020

Organisation Mondiale de la Santé Animale
World Organisation for Animal Health
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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

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1.

Introduction to substandard and falsified veterinary products

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What type of veterinary products are we talking about?

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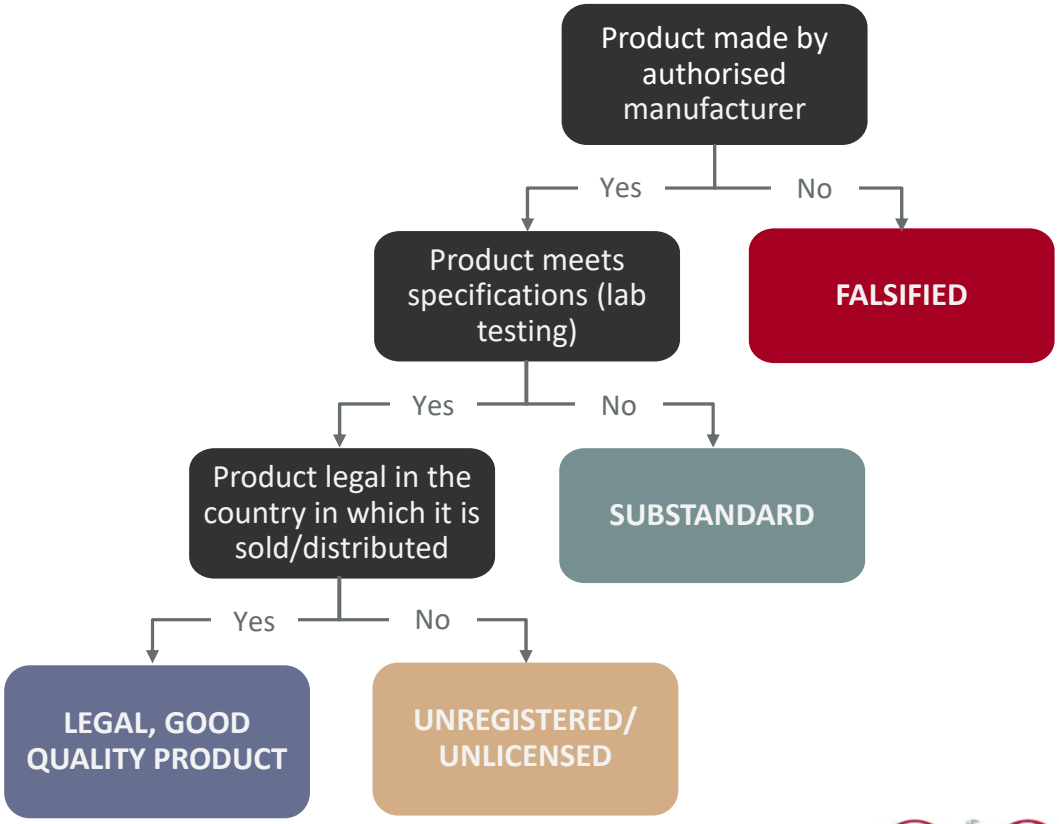

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The importance of veterinary product quality

Potential consequences include:

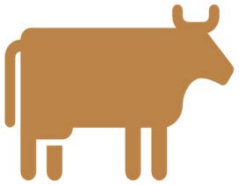
- Untreated illness (or preventable illness)
- Poisonings
- Loss of faith in veterinarians when treatments don’t work
- Contribution to the development of antimicrobial resistance

Interest in veterinary product quality 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."

OIE

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Current situation of substandard and falsified veterinary products

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Assessment of the current situation

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

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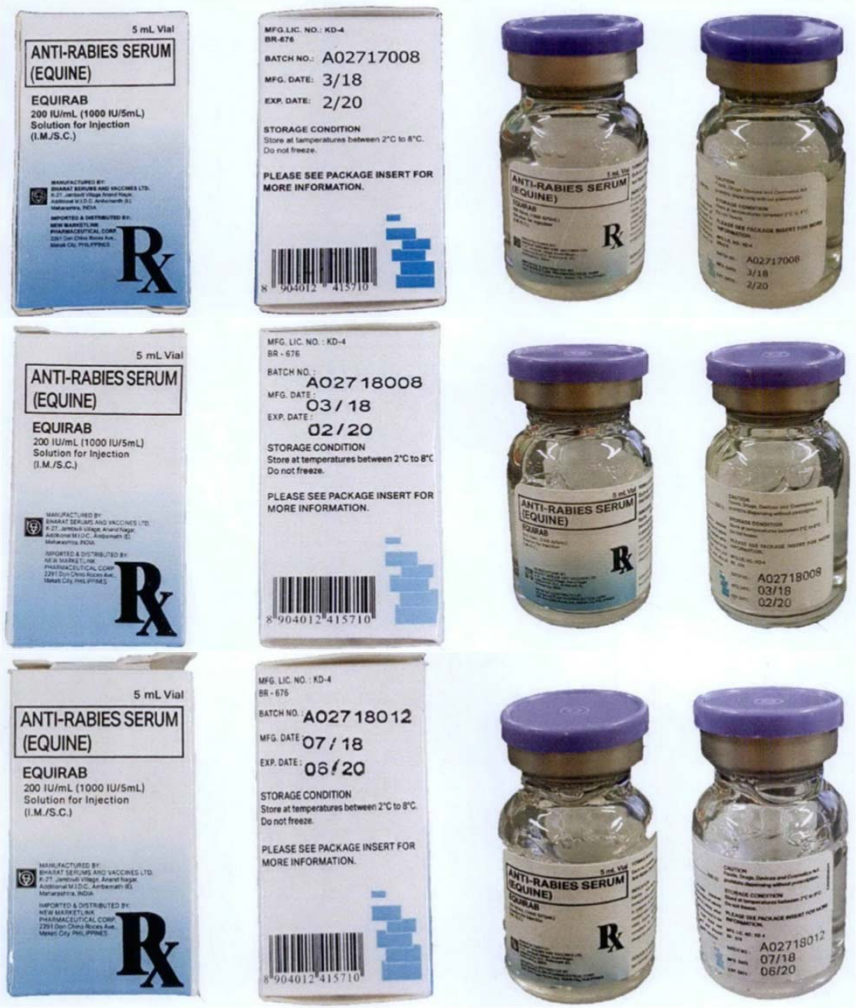
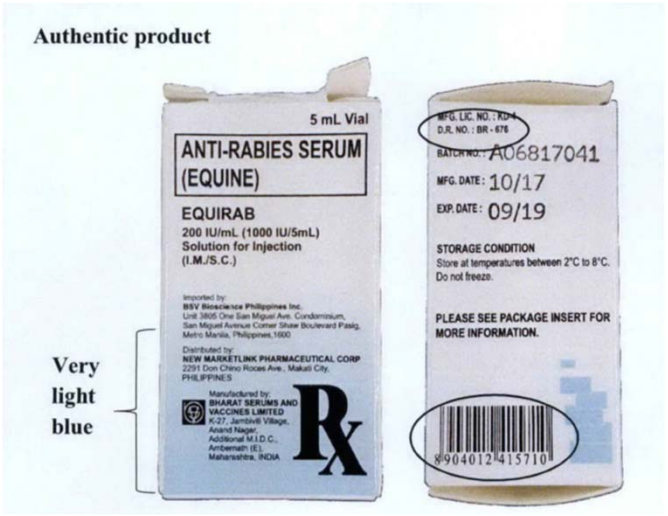
Assessment of the current situation

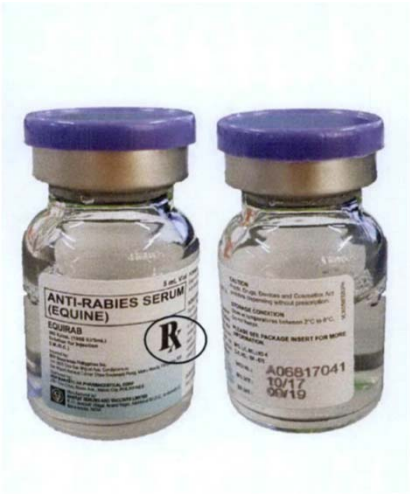
What causes the problem of SF veterinary products?

- 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







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Surveillance of substandard and falsified veterinary products

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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

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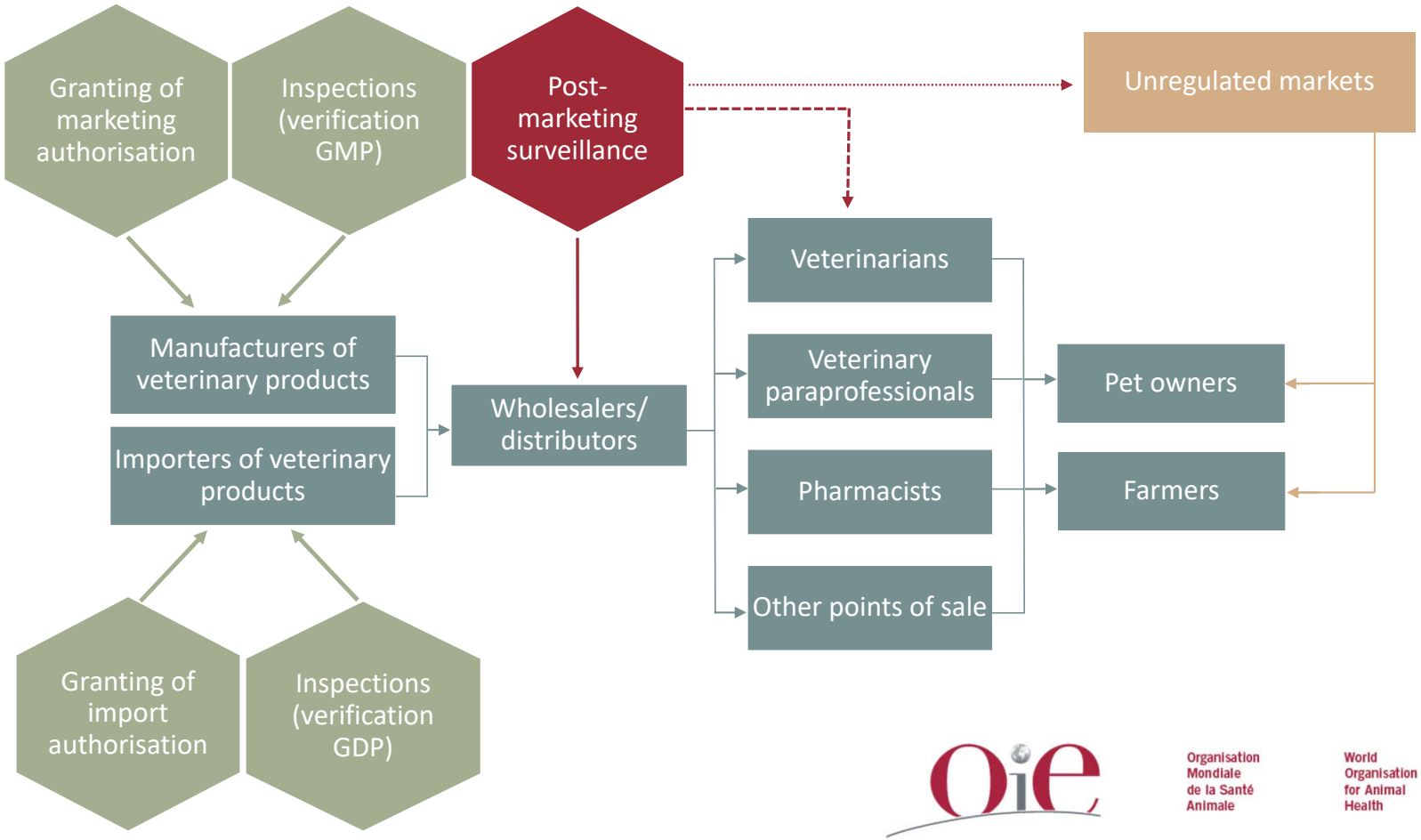
Active surveillance at a national or regional level



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3.

Potential for a global surveillance system of substandard and falsified veterinary products

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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

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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

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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

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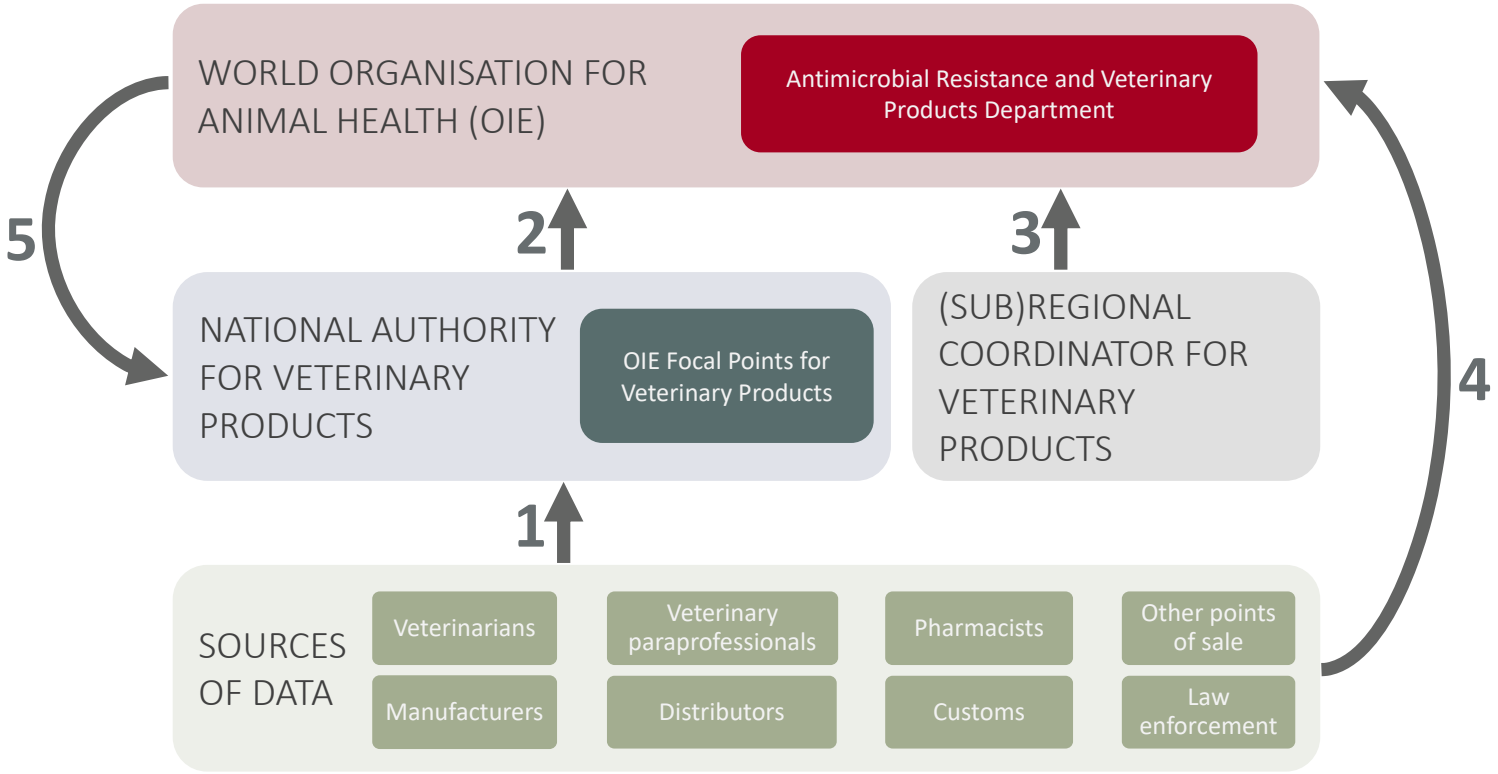
How could an OIE system function?

- 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

Organisational Structure (Draft)



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Data management

Data collection	Data processing	Data analysis	Data dissemination
Focal Points notifications Regional coordinators Other institutions/ individuals	Data processed within 48 hours Validation of data by OIE, including follow up with Focal Points	Identify patterns of incidents Consider alongside AMU data Better understand the global picture	Alerts (for high risk incidents) Annual reports Eventually, a searchable database

Preliminary steps

Collect feedback from OIE Member Countries – today's discussion!

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

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Preliminary steps

Draft questionnaire for discussion and future piloting

Immediate notification form

OIE Immediate Notification Form for 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 it in with the information that you do have. Follow up information can be sent through by email to <insert email> and will be added to the incident file.
If you have more than one product associated with this incident, once you have completed this page, you can use Form 1 (Product 2) to complete the same details for the next product (and for products 3-10). If you have more than 10 products, please email us.

	A. Reporting Agent	
1	**Title**	<free text field>
2	**Name (First name, SURNAME)**	<free text field>
3	**Role with respect to the OIE**	☐ OIE Delegate ☐ OIE Focal Point for Veterinary Products ☐ Other
4	**Organisation**	<free text field>
5	**Organisation's Address**	<free text field>
6	**Country**	<free text field>
7	**Phone Number**	<free text field>
8	**Email Address**	<free text field>
9	**Is this report related to an incident you have previously reported to us?**	☐ Yes ☐ No
10	**Are you willing for the information in this report to be shared with other OIE Focal Points for Veterinary Products?**	☐ Yes ☐ No
	B. Details of Suspect Veterinary Product (Product 1)	
	Questions 11 to 27 relate to the details of the veteirnary 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 found with no packaging, please respond with "no packaging", for questions 9-17 and move directly to section C.	
11	**Name of suspect product (brand name)**	<free text field>
12	**Active ingredient(s) (generic name) and strength**	Active ingredient 1 — Strength of active ingredient 1 *Active ingredient 2 (if applicable) — Strength of active ingredient 2 (if applicable)* *Active ingredient 3 (if applicable) — Strength of active ingredient 3 (if applicable)* *Active ingredient 4 (if applicable) — Strength of active ingredient 4 (if applicable)* *Active ingredient 5 (if applicable) — Strength of active ingredient 5 (if applicable)*
13	*Pharmaceutical form*	*Please select option from dropdown menu*
14	*Method of administration*	*Please select option from dropdown menu*
15	**Manufacturer**	<free text field>

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 it in with the information that you do have. Follow up information can be sent through by email.

	A. Reporting Agent	
1	**Title**	<free text field>
2	**Name (First name, SURNAME)**	<free text field>
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7	**Phone Number**	<free text field>
8	**Email Address**	<free text field>
	B. Information on incidents of substandard and falsified veterinary products	
9	**Were there any incidents of suspected or confirmed substandard or falsified veterinary products found in your country this year?**	☐ Yes, and the incident(s) has/have been notified to the OIE ☐ Yes, but the incident(s) has/have not yet been notified to the OIE ☐ No incidents of suspect or confirmed SF veterinary products were found
10	*If you answered yes to question 9, but have not yet provided these details to the OIE, please let us know any barriers to reporting this incident that you faced. Please also complete a notification form for these products <insert link>*	<free text field>
11	**Did you cooperate with any other countries in managing a suspected substandard or falsified veterinary product this year?**	☐ Yes ☐ No
	B. Country information on management of quality of veterinary products	
12	**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:* <free text field>

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Project proposal on quality of veterinary products

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

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Chargée de mission

Quality of veterinary products

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