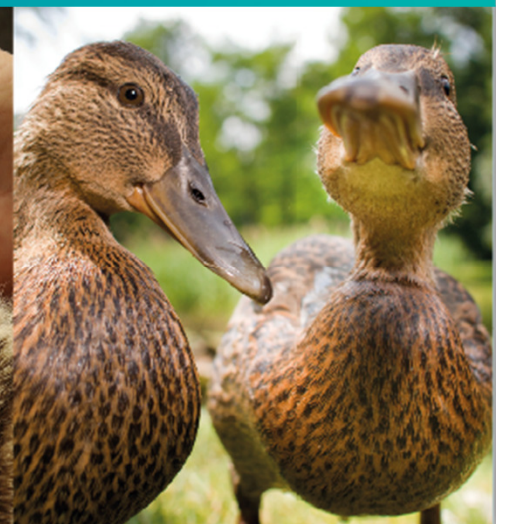


Quality of veterinary medicines

Regional Seminar for OIE National Focal Points for Veterinary Products

Entebbe, Uganda, 1-3 December 2015

Olivier Espeisse (Elanco), speaking on behalf of HealthforAnimals



1. What is HealthforAnimals? (2 slides)

2. Achieving quality (6 slides)

3. Counterfeits and fakes (5 slides)

What is HealthforAnimals?



- **global representative body of companies and associations**
- **R&D, manufacturing and commercialisation**
- **veterinary medicines, vaccines and other animal health products**

Animal health companies provide value to society:

- **by protecting animals and humans from diseases**
- **our products help keep pets and food-producing animals healthy**
- **public health benefits we bring include:**
 - **safer and more secure food supplies**
 - **more efficient production for increased food supply**
 - **improved sustainability**
 - **prevention of the transmission of zoonotic diseases**

Who are HealthforAnimals members?

Top 10 global companies



Bayer HealthCare



80+% global animal health sector

29 Regional associations

NORTH AMERICA

Canada
Mexico
United States

EUROPE and AFRICA

Europe
Belgium
Denmark
France
Germany
Ireland
Italy
Netherlands
Portugal
Spain
Sweden
Switzerland
United Kingdom
South Africa

CENTRAL/SOUTH AMERICA

Argentina
Brazil
Chile
Paraguay

ASIA/PACIFIC

India
Australia
Indonesia
Japan
Korea
New Zealand
South-East Asia
Thailand

The associations also represent hundreds of medium-sized and smaller companies.

Achieving quality (1)

Quality: why is it important?

Its important for farmers:

- if veterinary products don't work as they should, farmers lose animals
- lost animals = lower productivity = lost income

Its important for producers, who are:

- responsible to ensure quality in design, development, manufacturing, distribution
- ensure that all sources of variability affecting a process are identified and managed
- producers' reputation

Its important for society:

- poor products = poor production (meat, milk, eggs) = lower national productivity
- reputational risk for country damages export capacity
- disease spreading threatens other regions and countries
- consumer health risk of poor quality or fake drugs (residues and zoonosis)
- environmental risk

Achieving quality (2)

Challenge: Meeting regulatory requirements

Compliance with laws

- Good Manufacturing Practice or local manufacturing standards
- regulatory information update and information collection
- internal compliance system (check and balance)

Distribution requirement

- local company involvement (e.g. restriction on vaccines)
- Infrastructure for delivery (e.g. special storing condition, narcotic product, and toxic product)

Traceability

- product identification and record of delivery

Training and record system

- at the regulation change
- periodical reminding
- new staff addition, and new roles

Achieving quality (3)

Challenge: Meeting Good Manufacturing Standards (GMP)

- consistent quality - control of manufacturing processes
- appropriate quality - fit for purpose and not gold plated
- manufacturing specification - critical quality parameters for each product

Basic GMP requirements

- documented quality system – SOPs & records
- personnel qualifications, training, defined responsibilities
- premises and equipment
- control of raw materials
- control of production processes
- quality control testing and batch release certification
- inspection by authorities and internal audits

Achieving quality (4)

Challenge: Maintaining the product quality through distribution

Label/Packaging

Requirements

- description (contents, size, etc.)
- language (local, multi-language label, etc.),

Storing and Distribution condition

- definition of room temperature
- shipping condition (hot and cold temperature)
- feed formulation
- appropriate storage facilities(wholesaler/distributor/retailer/user)

Authorization of distributors

- consistent to global or local specifications
- local authorization of distributors and their premises
- additional local quality test by some countries

Achieving quality (5)

Challenge: Appropriate and safe use for animals and humans

Required product information / instruction transfer

- e.g. treatment withholding period - especially for exporting livestock products
- difference on local vs. global needs

Pharmacovigilance and other monitoring

Remaining minimum expiry term

Prescription system

Emergency support: e.g. intoxication cases

Appropriate medication: mixing in feed

Achieving quality (6)

Other considerations

Distribution (products and people): not to be a cause of disease spread

Contingency Plan (Crisis management)

- product recall plan

Serious infectious disease (emergency case handling)

- regional collaboration for the stock and the use
- regional approval

Vet-only-Sales policy, Owner's choice, Diversion, Parallel import, etc.

Good Distribution Practice (GDP) for Human Medicines

- more than 35 GDP in the world

Counterfeit veterinary medicines (1)

What do we know?

- counterfeiting is criminal activity - difficult to detect, investigate, quantify
- information we do have is based on 3 types of sources:

1. Law enforcement actions (and media coverage thereof)

- *“Seizure of counterfeit veterinary products”, 2013 China*
- *“Fake veterinary drugs on the market”, 2012 Uganda*
- *“Makers of fake veterinary medicine uncovered”, 2013 Vietnam*
- *“3 Sought in Counterfeit Veterinary Drugs Case”, 2006 USA*
- *“Giant UK Fake Veterinary Pharmacy Shut Down”, 2011 UK*

2. Some testing in some markets – extrapolation

- regular testing in developed markets by governments and others
- FAO, OIE, etc. projects in other markets, particular Africa

3. Industry experiences in the market place

- sense of likely sizes of markets
- reps visiting vets, distributors, farmers, etc.

Counterfeit veterinary medicines (2)

What can we conclude?

1. Widespread fake and sub-standard products in Africa

- Benin, Cameroon, Chad, Mali, Mauritania, Senegal, Togo = 40%+ sub-standard/counterfeit*
- Senegal: 67% of the analysed samples did not conform to quality requirements**
- Cameroon: 54 to 86% of samples did not pass quality requirements***

2. Different kinds of counterfeits – some worse than others

- benign – but allow disease to spread
- poisonous

3. Likely much less fakes in veterinary medicine vs. human medicine because:

- production animals - does not make economic sense to knowingly use substandard
- companion animals = people love them, why endanger their health knowingly?
- profit margins lower due to smaller scale of vet. market - less interesting for criminal gangs

4. Incentive to make, sell and use counterfeits exist in markets where:

- buyers are poorer and less informed about drawbacks
- criminal sellers are less likely to be caught/punished

* Source: Animal Trypanosomosis: Making trypanocidal drug quality control possible, to appear in Dec. 2014 OIE Review

**Source: Walbadet, 2007, The Evaluation of the quality of vet drugs in Senegal

***Source: Moustapha Ndottiwa, Veterinary Thesis, Rabat, 2008. Evaluation of the quality of vet drugs in Cameroon

Counterfeit veterinary medicines (3)



Example of fake veterinary products



Veterinary drugs sold in an African village market

(source of photos in presentation: Dr. Albert Doufissa. Presentation "What is Needed to Improve Availability to Good Quality Veterinary Drugs and Vaccines.")

Counterfeiting of veterinary medicines in some geographies is a reflection of the sophistication of the market.

Understanding the markets where counterfeiting happens

Farmers and veterinary services

- access to quality medicines is poor in remoter areas
- poorly funded local research institutes
- lack of awareness among livestock farmers - focus on price

Distributors/importers

- weak distribution channels
- interest of small distributors is financial, not quality or return customers
- poor financial capacity of importers
- packaging of drugs is a limiting factor
- administrative procedures for imports long and bureaucratic

Authorities

- no government policies or resources
- inadequate regulations and enforcement - lack of governance
- existing regulations not implemented (e.g. medicine registration in the countries)
- solutions (medicines/vaccines) do not exist or not up to date

Counterfeit veterinary medicines (5)

Industry position

- industry supports efforts by OIE, FAO, vet. authorities, law, etc. to combat fakes
- counterfeits threaten animal health = no therapeutic effect or toxicity
- possible harmful effects on humans = non-respect of MRLs + toxic material in foods
- counterfeits damage industry = customers not buying our products + negative image

Example of joint industry activity

- 2012 FAO/OIE/HealthforAnimals joint project to combat counterfeits to treat trypanosomosis

An effective fight against counterfeiting – to get quality medicines

1. formally registered pharmaceutical standards
2. political commitment to better animal health management
3. implementation/enforcement of existing regulations
4. development/availability of high quality veterinary services
5. training of vets and farmers
6. harmonised registration systems to ease import/enforcement
7. professional and sustainable importers/distributors


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Thank you