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Chargée de mission

The OIE activities to protect animal and human health: Potential contributions in the fight against counterfeit drugs

WCO Knowledge Academy
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Summary

- Problem statement: counterfeiting drugs
- OIE in brief (history and mandate)
- OIE National Focal Points for VMPs – Contribution to fight counterfeit products, what can be done together?
- Conclusion

Chapter 1

Problem statement: counterfeiting drugs

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Objectives

- Need a joint effort among regulatory bodies involved in human/veterinary medicinal products, customs and pharmaceutical industry and national and international level.
- **Open question:**
How can the OIE, World Customs Organisation, and enforcement agencies collaborate most productively, in partnership with the relevant stakeholders, to decrease and eventually eliminate the trade in falsified/counterfeit products?

Falsified vs. counterfeit medicines

Falsified medicines are not the same as counterfeit medicines (human):

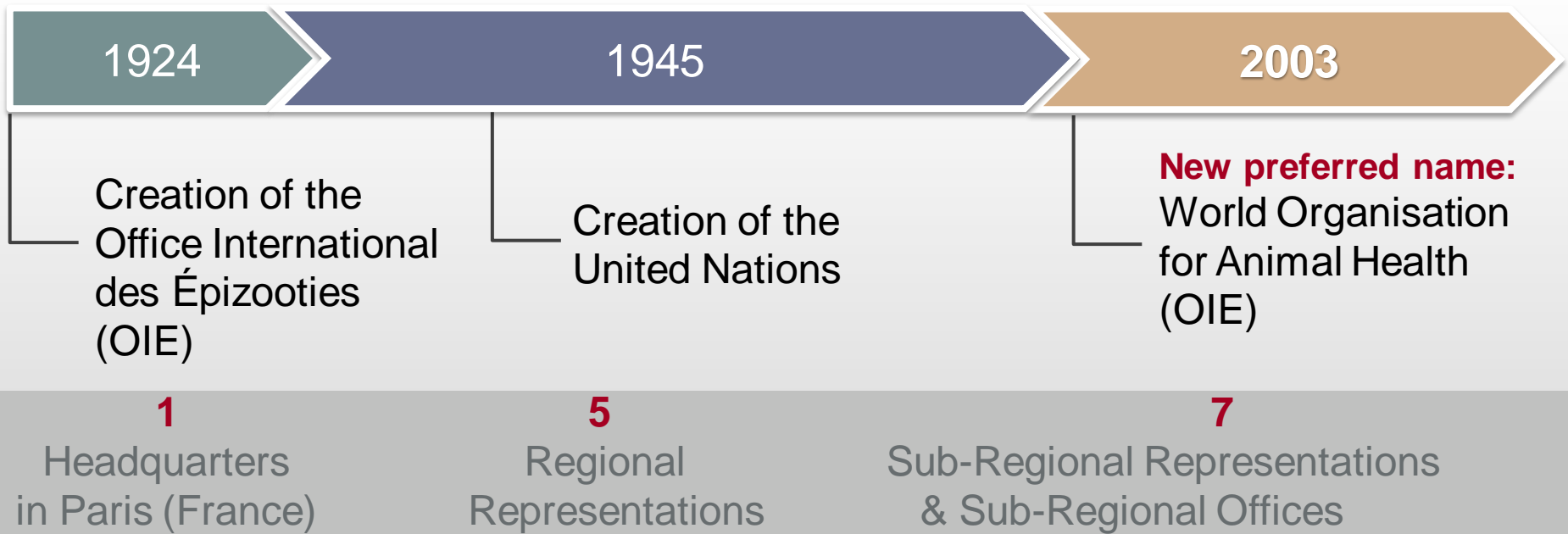
- **Falsified medicines** are fake medicines that are designed to mimic real medicines.
- **Counterfeit medicines** are medicines that do not comply with intellectual-property rights or that infringe trademark law.

THE OIE IN BRIEF

World Organisation for Animal Health

History

An intergovernmental
technical and science-based Organisation



Who we are today...

Improving animal health and welfare worldwide



STANDARDS

for international
trade of animals
and animal
products



TRANSPARENCY

of the world
animal disease
situation



EXPERTISE

Collection and
dissemination of
veterinary
scientific
information



SOLIDARITY

between
countries to
strengthen
capacities
worldwide



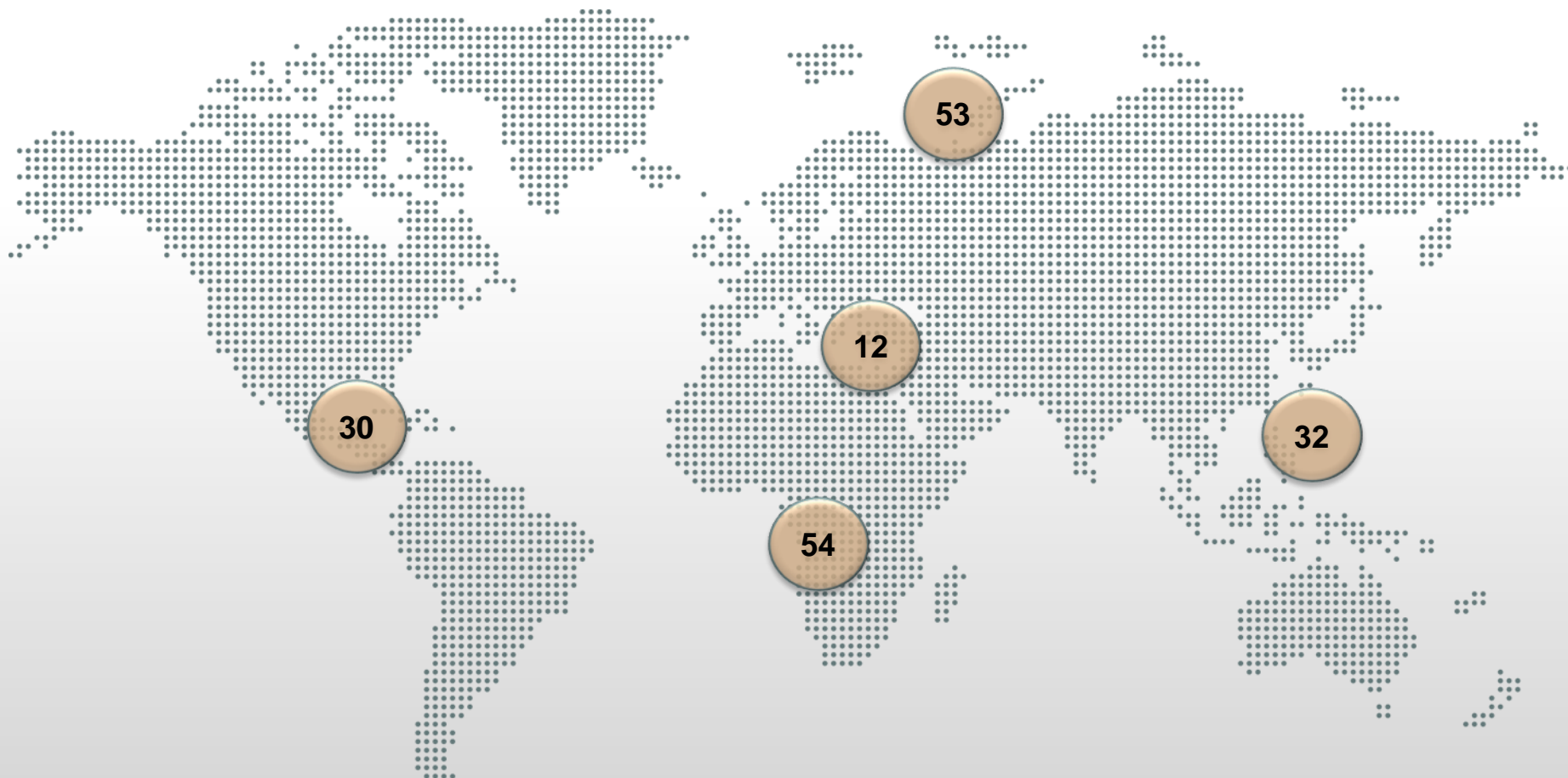
*under the mandate
given by the WTO*

including zoonoses

*animal disease prevention
and control methods*

*Capacity building tools
and programmes*

181 Member Countries in 2017



The “One Health” Concept

A global strategy for managing risks at the
Animal - Human - Ecosystems interface



Tripartite agreement of 3 Directors General

3 Priorities



Zoonotic influenzas

⇒ OFFLU, OIE/FAO
expertise network on animal
influenza

Antimicrobial resistance

⇒ The OIE action plan
contributes to the achievement
of certain issues in the WHO
Global Action Plan

Rabies Global control of canine rabies

⇒ WHO-OIE global
conference in
Dec. 2015

Antimicrobial Resistance

AMR

- Antimicrobial resistance is induced by repeated exposure to sub-lethal or sub-optimal concentrations of an antimicrobial ingredient, leading to resistance in subsequent generations of surviving populations of bacterial or parasitic species.

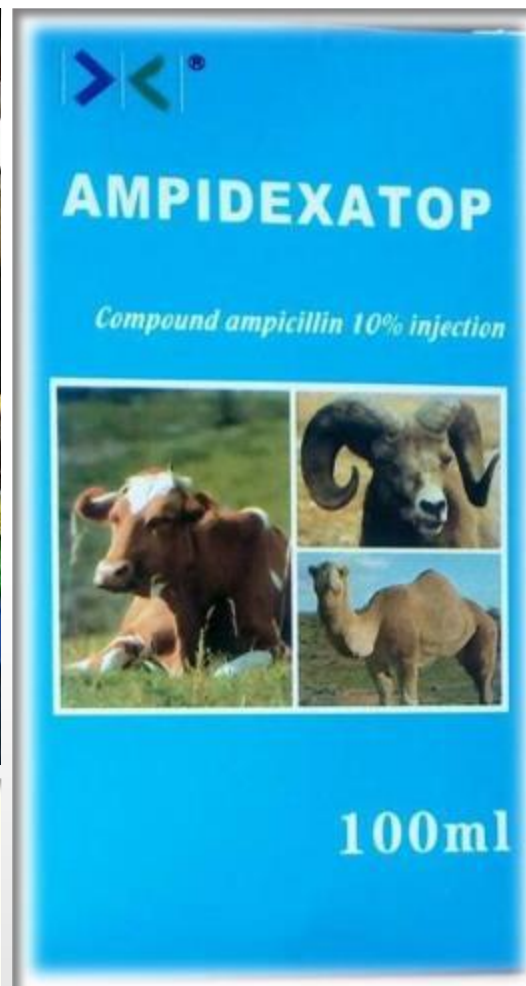




Antimicrobial Resistance

AMR

- Need quality assured, safe and efficient veterinary products (VMPs)
- The counterfeit or sub-standard, not -authorised drugs could lead to the development of antimicrobial resistance



**Falsified/counterfeit
antibiotic**



Antimicrobial Resistance

AMR

- Many countries do not have legislation and specific guidelines for authorisation/registration of VMPs
- Lack of enforcement of existing legislation
- Low level of penalties or sanctions
- Inefficient cooperation between stakeholders

Antimicrobial Resistance

AMR

Barriers categories that impeded to report quantities of antimicrobial agents in animals in 39 OIE Member Countries in 2016



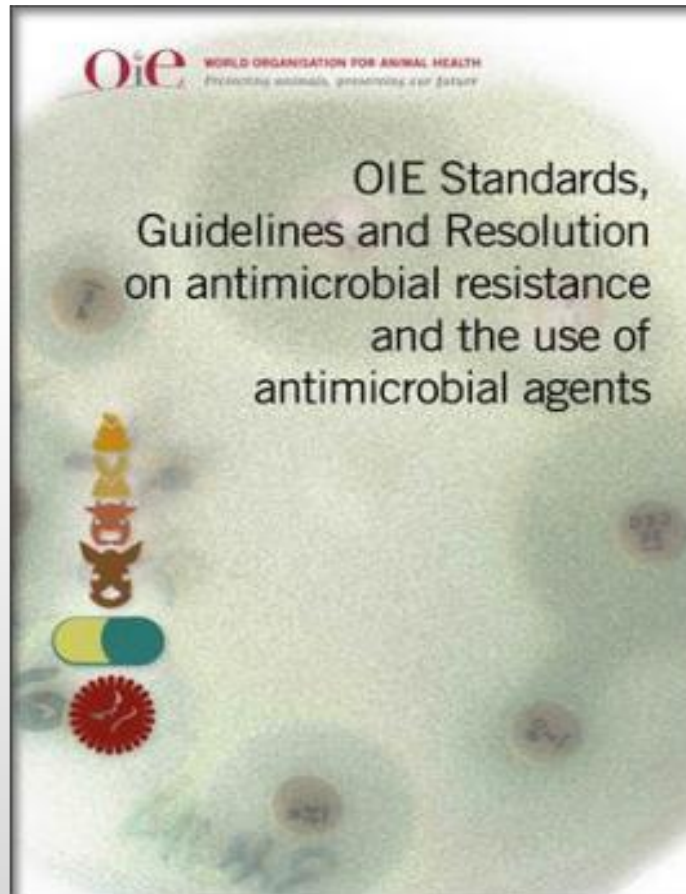
Antimicrobial Resistance

AMR

INSUFFICIENT REGULATORY ENFORCEMENT:

- Two Member Countries, with barriers belonging to other categories, have stated that the illegal veterinary products on the market do not allow quantities of antimicrobials agents in animals to be reported. One country mentioned the main barriers on why quantitative data are not available are: unlicensed manufacturers and use of veterinary products on the field by unauthorised persons.

Standards and guidelines related to antimicrobial resistance (AMR)



Chapter 3

OIE National Focal Points for VMPs – Contribution
to fight counterfeit products, what can be done
together?

National Focal Points

8 areas of expertise

Aquatic animals

Communication

Wildlife

Animal welfare

Animal disease notification

Animal production food safety

Veterinary products (including AMR)

Veterinary Laboratories

Appointed by the Delegate

National Focal Points

Veterinary Product-AMR

- Focal Points for Veterinary Products (VP)
- Regional Training Seminars:
- Africa, Asia and Europe in 2015 and 2016
 - Uganda 1-3 December 2015 (total n. 30)
 - Japan 2-4 March 2016 (total n. 54)
 - Senegal (21-23 March 2016 (total.n24)
 - Budapest (11-13 October 2016 (total. N53)

National Focal Points

Veterinary Product-AMR

- **One of the main objectives of the 4th cycle Seminar – counterfeit products:**
 - Quality of veterinary drugs - how to ensure the quality of veterinary medicinal product (VMP) ?
 - **Fight against counterfeit product drugs**
 - Counterfeit products/drugs experience
 - Possible solutions and needs

CONCLUSION

Question for Future Discussion

- How can the OIE and World Customs Organisation collaborate most productively, in partnership with the relevant stakeholder(s), to decrease and eventually eliminate the trade in falsified/counterfeit products?
- What practical feasible approach specific action can be done ?



WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

Thank you for your attention

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