



Jane Lwoyero

Programme Officer

Sub-Regional Representation for Eastern Africa

World Organisation for Animal Health

VICH and Veterinary Medicines availability
Improvement of global animal and human health

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Cape Town, South Africa
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Agenda

- Introduction
- OIE and Veterinary Medicinal Products
- Availability of Veterinary Medicinal Products
- Improving Animal and Human Health
- Conclusions

Chapter 1



Introduction

Introduction

- The OIE's international standards on animal health and welfare are designed to prevent and control animal diseases (including zoonoses), ensure the sanitary safety of traded animals and their products and to safeguard animal welfare;
- *Veterinary medicinal products* (VMP) are important tools in the prevention and control of animal diseases.

Introduction

- VMPs are essential to protect human and animal health, as well as animal welfare;
- Regulation of authorisation, manufacturing, distribution and use of veterinary products ensures effective and sustainable animal disease control while minimising risks to humans and animals.

Chapter 2



The OIE and Veterinary Medicinal Products (VMP)

OIE and Veterinary Medicinal Products

The OIE...

- Develops international standards and guidelines and recommendations for:
 - veterinary products, mainly vaccines for the control of OIE listed diseases (*OIE Manual*);
 - the responsible and prudent use of antimicrobials (*OIE Codes*) so as to preserve their therapeutic efficacy and prolong their use in both animals and humans.

OIE and Veterinary Medicinal Products

The OIE...

- Trains national focal points for veterinary products (which include diagnostic kits).
- Promotes activities related to the harmonisation of veterinary legislation and provides support to veterinary services (including laboratories) to enable Member Countries (“Members”) to implement standards, guidelines and recommendations.
- Circulates the VICH Guidelines to Members

International Organisations with Agreements with the OIE (VMP)

- World Customs Organisation (**WCO**)
- Health for Animals (formerly IFAH)
- Organisation for Economic Cooperation and Development (**OECD**)
- Inter-american Institute for Cooperation in Agriculture (**IICA**)
- International Air Transport Association (**IATA**)

International Organisations with Agreements with the OIE (VMP)

- World / Pan American Health Organisation (WHO / PAHO)
- World Intellectual Property Organization (WIPO)
- International Association for Biologicals (IABs)
- Global Alliance for Livestock Veterinary Medicines (GALVmed) *being renewed*

Regional Organisations with Agreements with the OIE (VMP)

- Arab Magreb Union (**AMU**)
- Inter-Governmental Authority on Development (**IGAD**)
- Southern African Development Community (**SADC**)
- West African Economic and Monetary Union (**WAEMU**)

GALVmed – OIE Stakeholder workshop

on the harmonisation of the registration of veterinary medicinal products (SADC).
Johannesburg, South Africa 9 – 11 May 2017

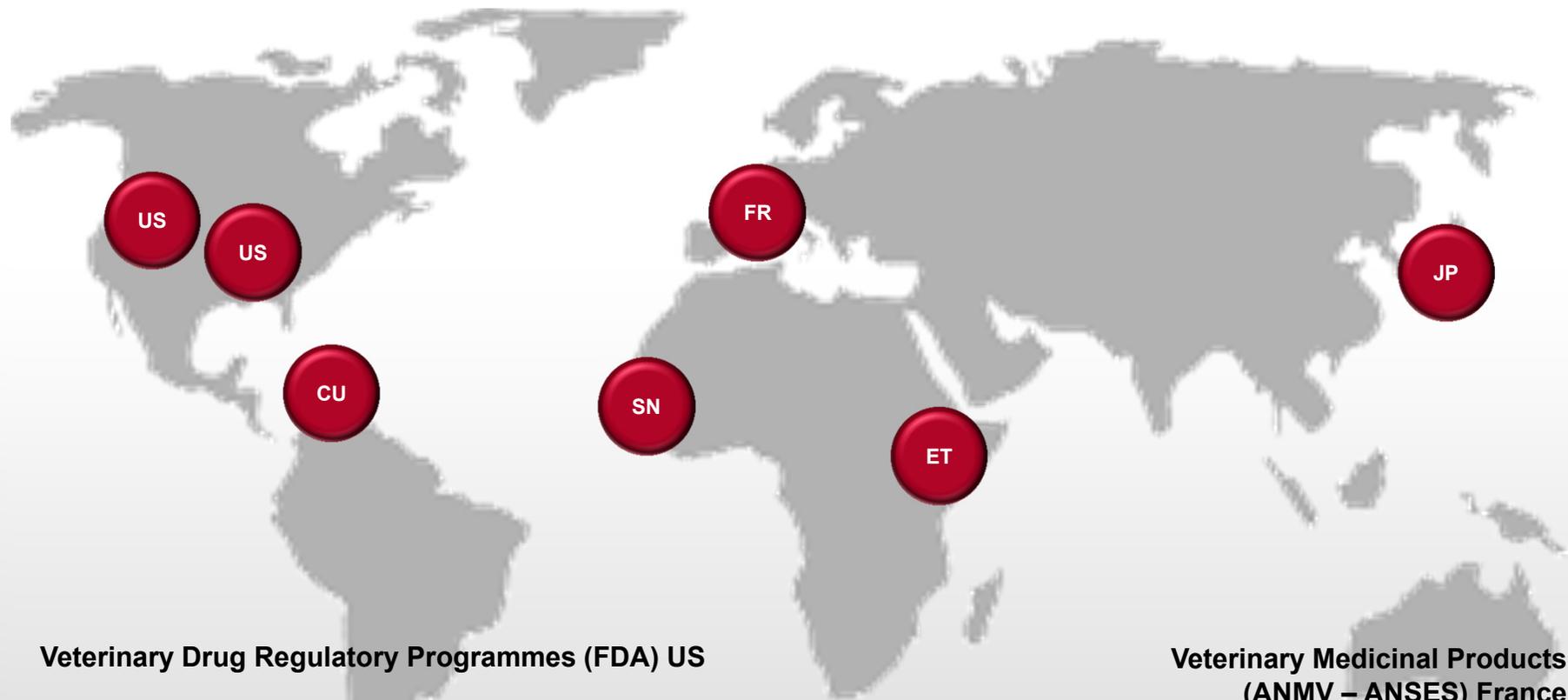


Progress on the recommendations to OIE

of the GALVmed and OIE meeting to promote harmonised registration of veterinary drugs in the SADC region.

- Chapters 1.1.8, 1.1.9, 3.4, and 3.7. of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals have been translated to French (now online);
- OIE Twinning programmes for laboratories and collaborating centres allows countries to increasingly access high quality diagnostic testing and technical know-how within their own region.

OIE Collaborating Centres (VMP)



Veterinary Drug Regulatory Programmes (FDA) US

**Diagnosis of Animal Diseases and Vaccine Evaluation
in the Americas (IICAB + USDA) US**

**Development and Production of Vaccines,
Pharmaceutical Products and Veterinary Diagnostic
Systems using Biotechnology (CIGB) Cuba**

**Veterinary Medicinal Products
(ANMV – ANSES) France**

**Control of veterinary drugs in West
and Central Africa (EISMV) Senegal**

**Quality Control of Veterinary Vaccines
(AU-PANVAC) Ethiopia**

**Diagnosis and Control (...) Related Veterinary Product
Assessment in Asia (NIAH – NVAL) Japan**

Progress on the recommendations to OIE

- OIE supports countries to modernise veterinary legislation and has developed a standard to guide Veterinary Services (Chapter 3.4 of the Terrestrial Animal Health Code) which includes article 3.4.11. on *Veterinary medicines and biologicals*

Progress on the recommendations to OIE

- Aspects of registration/authorisation of VMPPs has been incorporated in the ongoing capacity-building programmes including training seminars for OIE Focal Points for Veterinary Products.

Next (Cycle VI) *Addis, Ethiopia, 9 – 11 July*

www.rr-africa.oie.int/en/news/20170517.html

Chapter 3



Availability of Veterinary Medicinal Products

Veterinary medicines availability

- Control of animal disease threats to the health and welfare of animals cannot be achieved without the judicious use of VMPs
- Irresponsible use of VMPs has harmful consequences, for animal and public health and environment:
 - Failure of treatment or prophylaxis;
 - Residues of veterinary drugs in food products derived from animals;
 - *Antimicrobial resistance (AMR)*.

Veterinary medicines availability

Harmonised Regional Technical Regulations...

- Promote good governance of VMP;
- Minimise the cost of gaining registration hence improving access to effective and safe VMP;
- Ensure market authorisation is given only for safe, efficacious and quality-assured registered VMP.

Chapter 4



Improving Animal
and Human health

Improving Animal and Human Health

- Availability of safe and quality-assured VMPs guarantees predictable treatment outcomes and minimises the impact of diseases using appropriate treatment;
- Predictable outcomes and evidence-based treatment optimises use of VMPs, reducing misuse of antimicrobials hence reduces the pressure of emergence of AMR;
- Reduction in repetitive animal studies in VMP registration safeguards animal welfare.

Improving Animal and Human Health

- Synergies and complementarities between the *Joint External Evaluation* (JEE, 2d edition) tool and the OIE's *Performance of Veterinary Services* (PVS) Pathway (6th edition), provides concrete information regarding the national veterinary services' contribution to specific core capacities defined in the IHR (2005).

Management of VMP by Vet. Services

- Performance of Veterinary Services (PVS)

Critical Competency II.9. Veterinary medicines and biologicals (6th Edition PVS Tool)

“The authority and capability of the VS to regulate veterinary medicines and veterinary biologicals, i.e. the authorization, registration, import, production, labelling, distribution, sale and use of these products”

May include *Competent Authorities (CA)*, e.g. NRA (MoH)

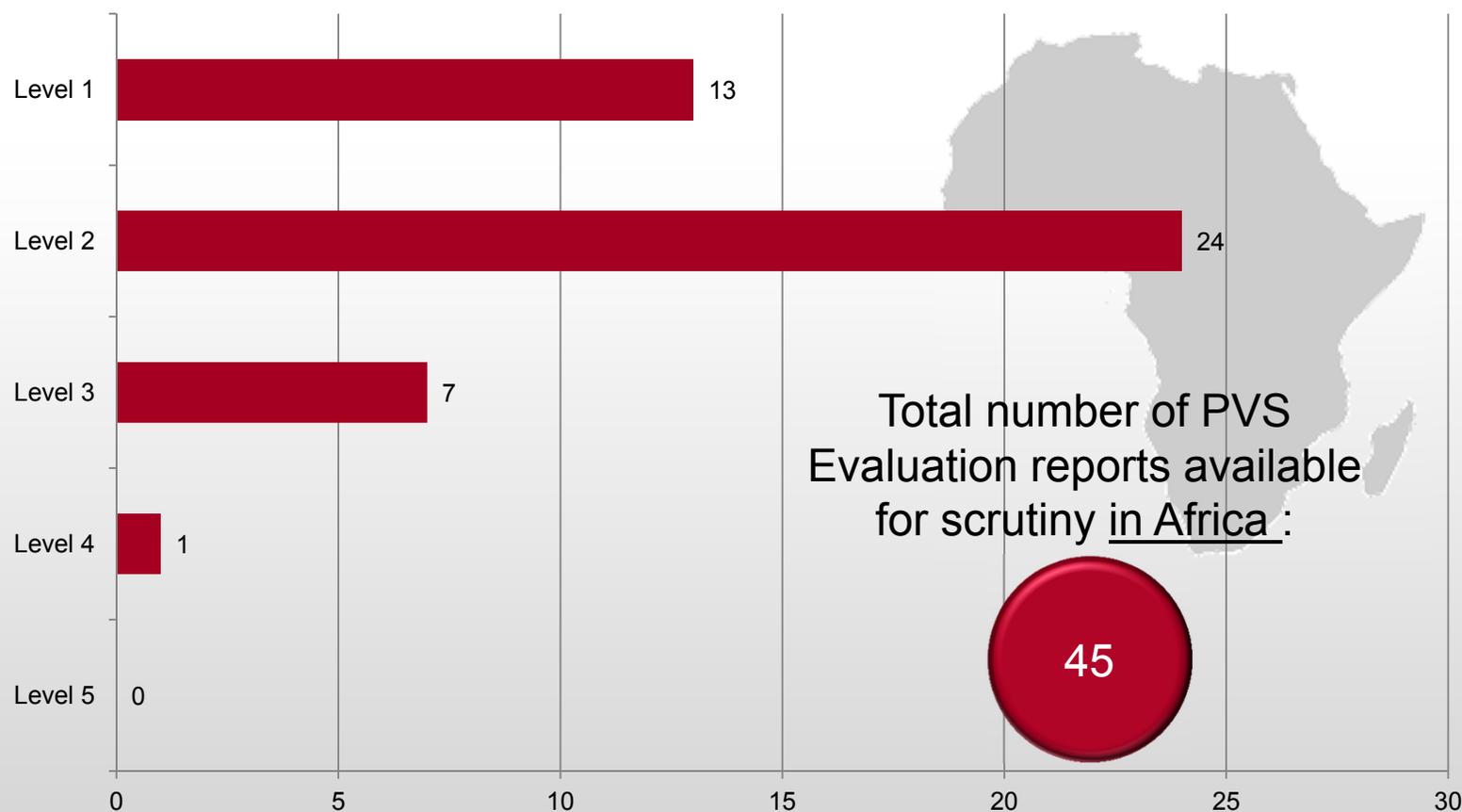
Management of VMP by Vet. Services

- Performance of Veterinary Services (PVS)

Level 1	No compliance	The VS cannot regulate veterinary medicines and veterinary biologicals.
Level 2	Minimal compliance	The VS have some capability to exercise administrative control over veterinary medicines and veterinary biologicals.
Level 3	Moderate compliance	The VS exercise effective administrative control and implement quality standards for most aspects of the regulation (...)
Level 4	Full compliance	The VS exercise comprehensive and effective regulatory control of (...)
Level 5	Exceeding benchmark	

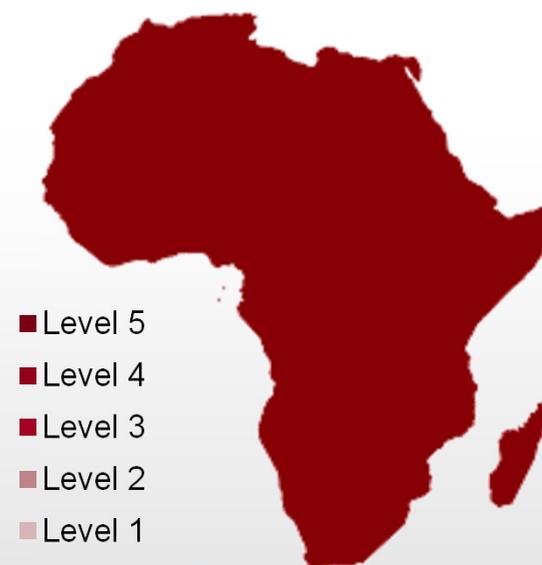
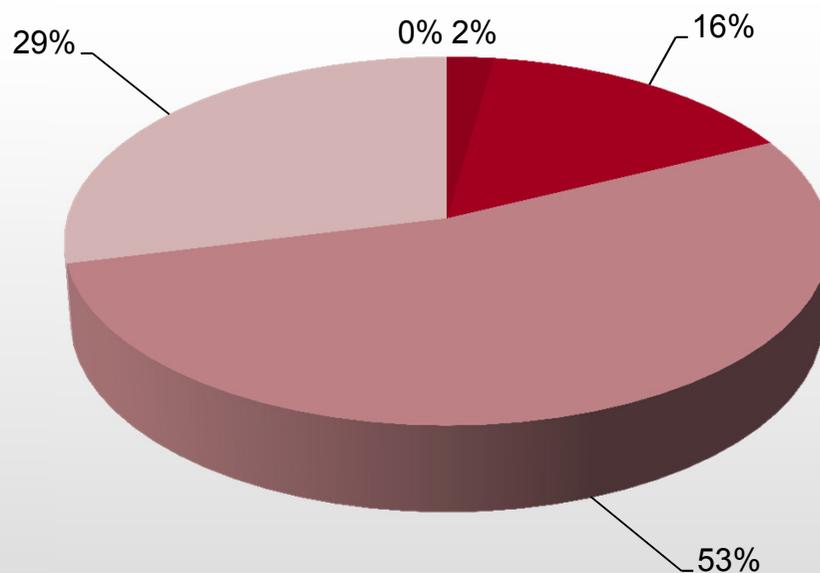
Management of VMP by Vet. Services

- Performance of Veterinary Services (PVS)



Management of VMP by Vet. Services

■ Performance of Veterinary Services (PVS)



Chapter 5

Conclusions

Conclusion

- Availability of good quality veterinary medicine will play a role in reducing the negative impacts of illegal and falsified veterinary medicine;
- Health and safety issues linked to use of illegal veterinary medicine include development of increased risk of lack of efficacy, spread of infection and AMR.

Conclusion

- Responsible use of available veterinary medicines promotes animal health and welfare, supports livelihoods by reducing poverty, improves food security, contributes to food safety and increases access to lucrative markets for animals and animal products while safeguarding public health.

Thank you for your attention



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WORLD ORGANISATION FOR ANIMAL HEALTH

Protecting animals, preserving our future

12, rue de Prony, 75017 Paris, France

www.oie.int

media@oie.int - oie@oie.int

