The contribution of VICH to the global One Health approach
Focus on antimicrobial resistance

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Context

- +1 billion people by 2050
- Focus on developing countries
- Demand for animal protein, increase by more than 50%
- Unprecedented movement of people and commodities

Demand for food
Population growth
Globalisation
Context
AMR: a major and global public health issue

“One World, One Health” Concept

General Principles:

- 60% of pathogens that causes diseases in humans are from animal origin…: zoonosis
- Animal in good health produce more animal-derived protein and play an important role in the World Food Program
- Animal in good health produce safe food
The “ONE HEALTH” concept ensure political support in coordinated prevention of high public health and animal impact diseases at the human-animal interface.
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
The tripartite FAO – OIE – WHO collaboration

- Global leader for food and agriculture
- Global leader for animal health and welfare standards
- Global leader for human health

Global Action Plan on AMR

- Tripartite document on *Stewardship and country consultation* (November)
- *Monitoring and Evaluation* (ongoing)
- Communication tools (Communication Unit)
- National Action Plans: *Tripartite questionnaire to monitor implementation*
The Tripartite united against AMR

First meeting of the Interagency Coordination Group (IACG) on Antimicrobial Resistance, New-York, 2-3 May 2017

Reporting back to the 73rd Session of the United Nations, June 2019
• **Mapping activities** against the Global Action Plan for Tripartite, other UN agencies, and the wider stakeholder community (NGOs, private sector)

• **Monitoring framework** for Global Action Plan and National Action Plans

• **Stakeholder management** system to provide channels for dissemination of information and coordination of activities

• **Effective advocacy** to retain awareness of AMR at the highest international and national political levels
Publication: OIE Strategy on AMR and Prudent Use of Antimicrobials

The OIE Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials

November 2016

http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/PortailAMR/EN_OIE-AMRstrategy.pdf
The OIE Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials

Context

- 2015 Global Action Plan on AMR and the Tripartite Partnership
- OIE World Assembly Resolutions on AMR in 2015 and 2016
- OIE Strategy launched in November 2016
- Outlines a consolidated work program under the following four key objectives aligned with the Global Action Plan:

1. Improve awareness and understanding
2. Strengthen knowledge through surveillance and research
3. Support good governance and capacity building
4. Encourage implementation of international standards
3) Support good governance and capacity building

- Provide assistance to Member Countries in developing and implementing **National Action Plans**, promoting a “One Health” approach

- **Provide tools and guidance** to assist Member Countries in their AMR risk assessment initiatives

- Ensure Veterinary Services have the capacity to implement OIE international standards, through engagement in the PVS Pathway

- Support Member Countries to **develop and modernise legislation** governing the **manufacture, marketing authorisation**, importation and distribution and use of veterinary products

- Provide regular training of **Focal Points on Veterinary Products**

- Ensure that **well-trained veterinarians and veterinary para-professionals** are at the forefront of national and regional efforts
4 Encourage implementation of OIE standards

- Support Member Countries in their efforts to **implement OIE standards**
- **Disseminate and encourage adoption of recommendations** in the OIE List of Antimicrobials of Veterinary Importance
- **Strengthen multilateral support** for implementation of OIE standards among policy makers
- Build on the success of the OIE standards development work programme to continue to advance for the animal sectors our **comprehensive framework of quality, science-based standards** that support the Global Action Plan on AMR
- **Collaborate with WHO and FAO** to support the development of a comprehensive and aligned framework of standards and guidelines across human health, animal health, agriculture and the food chain
“One World, One Health” Concept

- **Veterinary Medicinal Products (VMPs):**
  - are veterinary tools, contributing to the improvement of animal (and public health), and to economical development.

- **The VMPs policy is part of the animal health policy:** Vet Drugs shall be quality assured, safe and efficient
  - To protect **Animal health**
  - To protect **Human Health** (residue, zoonosis, AMR)
  - For **Environmental safety**
What do we need?

- International standards (to harmonise protocols and methodologies)
- Coordinated research on effectiveness of policies to achieve AMR risk reduction
- Legislation on access to quality drugs and restricted use
- Good governance of all sectors related to authorisation and use of VMPs (lab expertise, international standards and legislation development and implementation, surveillance and control)
Major International Standards
Harmonization Efforts for VMPs

WHO/FAO Codex Alimentarius
Commission → MRL

World Organisation for Animal
Health (manufacturing, quality
control, AMR…)

International Cooperation on
Harmonisation of Technical
Requirements for Registration of
Veterinary Medicinal Products
Good governance for good quality

MARKETING AUTHORIZATION:
- Definition of specifications
- Descriptions of the methods of manufacturing, control, etc.
- Establishments involved in the manufacturing...
- Benefit/risk balance

MANUFACTURE:
- Good manufacturing practices
- GMP certificate for establishments:
  - Quality management
  - Management of anomalies
  - Testing for product release
  - Complaints management

MARKETING:
- Good distribution practices
- Cold chain
- Advertising
- Quality defects
- Pharmacovigilance

USERS:
- Veterinary practitioners
- Farmers
- Animal owners
- Pharmacovigilance
- Quality defects

VICH GlS
GDP
GMP
GPVceP
BPG
Ethic Code

OIE Manual

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OIE and VICH

In the context of “One health” approach, for a better harmonisation, as presented by Dr Brückner, OIE strongly supports VICH work:

- in the 5\textsuperscript{th} strategic plan, OIE encourages the use of VICH guidelines;
- Supports the process of setting up the VICH Outreach Forum since the beginning.
Goals of VICH and contribution in One Health Concept

- The objectives of the VICH are along the same lines as those of the ICH
- VICH work takes particular note of the ICH work
- VICH establishes harmonised technical requirements for registration of veterinary medicinal products
- VICH develops Guidelines:
  - Study and testing methodology
  - Post-marketing safety monitoring medicines
Contribution of VICH: focus on AMR

VICH developed useful GLs to ensure good quality, safety and efficacy of VMPs:

- **Quality**: all GLs on quality ensuring good quality and stability of VMPs (GL1 to 5, GL 39…)
- **Ecotoxicity**: impact of environment: GL6, GL 38...
- **Safety**: GLs on reprotoxicity (GL 31), genotoxicity (GL37), … on residue (GL 32, GL 33)...
- **Pharmacovigilance**: GL24, 29, 30, 42…
Contribution of VICH: focus on AMR

VICH developed also specific GLs to contribute fight against AMR:

- **GL27**: guidance on pre-approval information for food producing animal with respect to AMR: outlines studies and data, recommended to characterize the potential resistance development as it might occur in the food-producing animal under the proposed conditions of use of the product. Description of the drug substance, the drug product, the nature of the resistance and the potential exposure of the gut flora in the target animal species,

- **GL36**: General approach to establish a microbiological ADI: (1) outline the steps in determining the need for establishing a microbiological acceptable daily intake (ADI); (2) to recommend test and methods for determining no-observable adverse effect concentrations and levels (NOAELs) for the endpoints of health concern; and (3) to recommend a procedure to derive a microbiological ADI.
CONCLUSION

Protecting animals, preserving our future

- AMR is a global and major public health issue.
- In the One Health context, OIE-FAO-WHO develop a tripartite collaboration.
- VICH contributes to ensure availability of sure, safe and efficient VMPs by establishing harmonised technical requirements for registration of veterinary medicinal products.
- VICH develops general Guidelines:
  - Study and testing methodology
  - Post-marketing safety monitoring medicines)
- But also specific ones for antimicrobial which contribute to fight against antimicrobial resistance.
Thank you for your attention

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