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

VICH 6<sup>th</sup> Public Conference

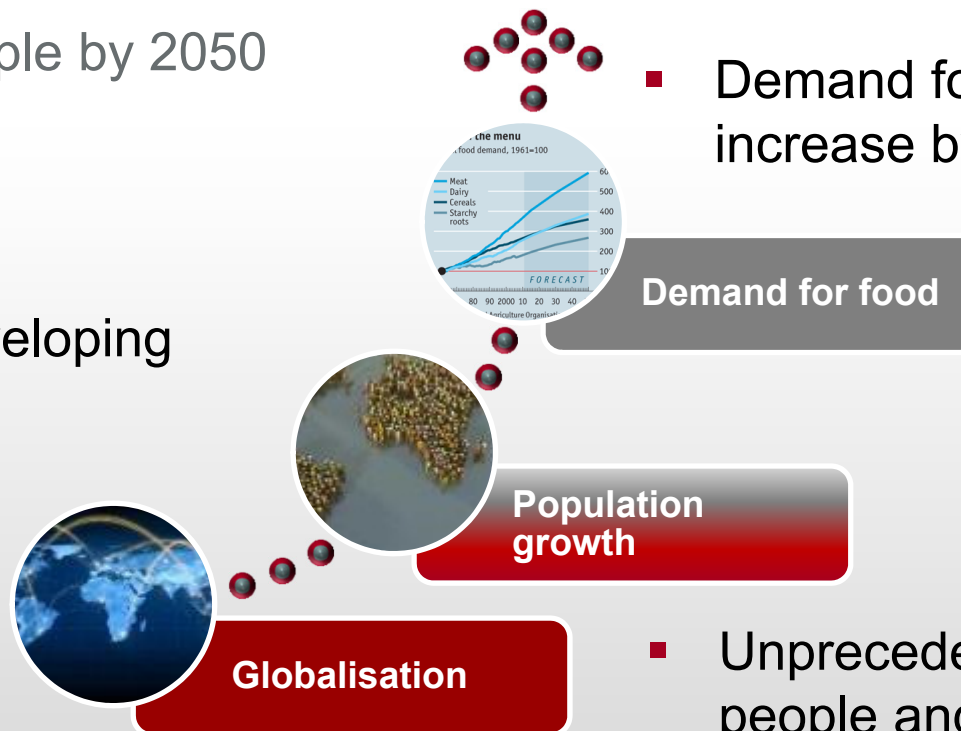
Cape Town, South Africa, 26-28 February 2019



# Context

- +1 billion people by 2050

- Focus on developing countries

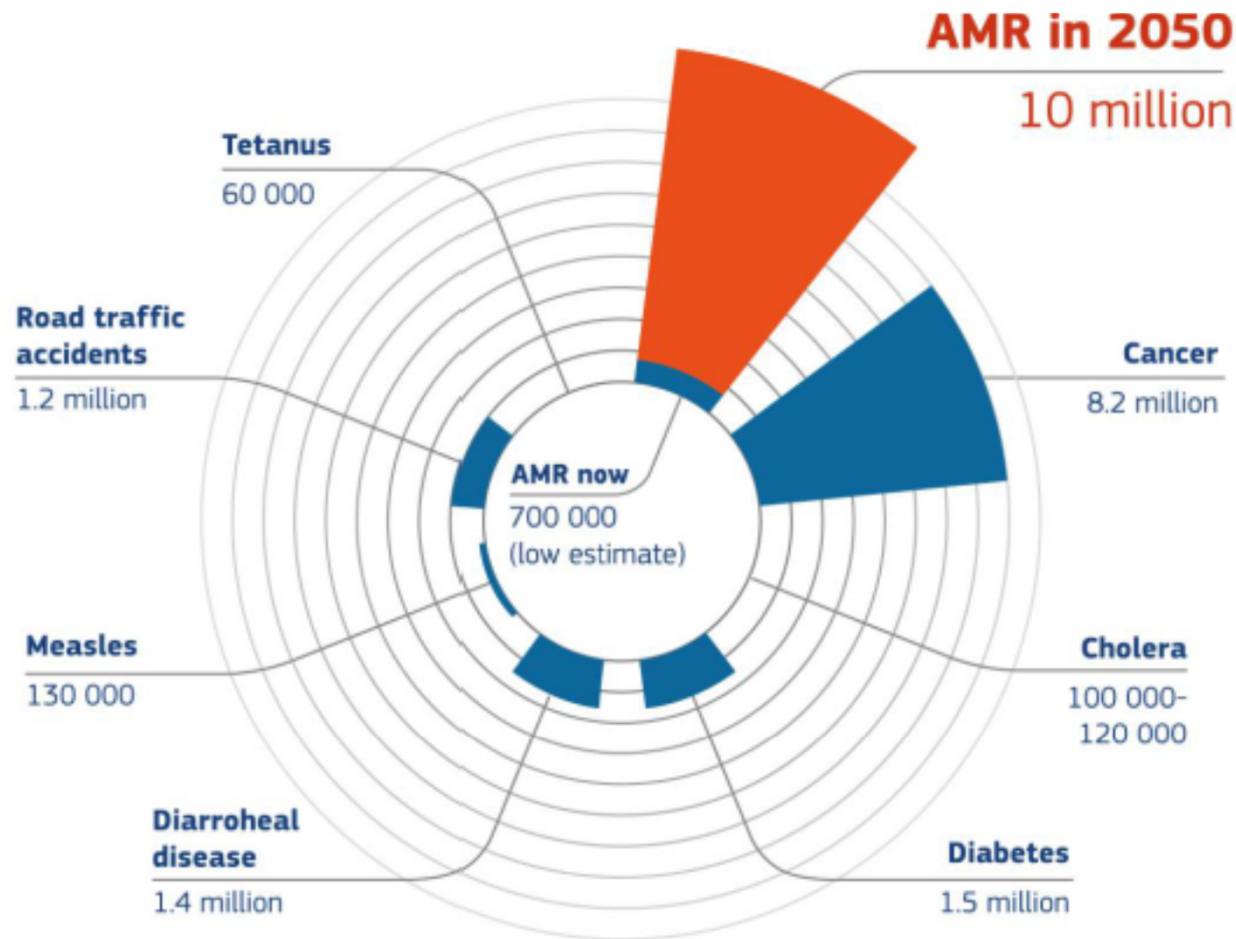


- Demand for animal protein, increase by more than 50%

- Unprecedented movement of people and commodities

# Context

AMR : a major and global public health issue



Source: *The Review on Antimicrobial Resistance*,  
Jim O'Neill, 2016

# “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

# “ONE WORLD, ONE HEALTH” CONCEPT



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



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

## 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



## HIGH-LEVEL MEETING ON ANTIMICROBIAL RESISTANCE



21 SEPTEMBER 2016, UN HEADQUARTERS, NEW YORK

- First meeting of the Interagency Coordination Group (IACG) on Antimicrobial Resistance, New-York, 2-3 May 2017
- Reporting back to the 73<sup>rd</sup> Session of the United Nations, **June 2019**



### Draft political declaration of the high-level meeting of the General Assembly on antimicrobial resistance

The Heads of State and Government and representatives of States and Governments, meeting at United Nations Headquarters in New York on 21 September 2016, in accordance with General Assembly resolution 70/185, in which the Assembly decided to hold a high-level meeting in 2016 on antimicrobial resistance:

1. Reaffirm that the blueprint for ending antimicrobial resistance in the World Health Organization global action plan on antimicrobial resistance<sup>1</sup> and its five overarching strategic objectives developed by the World Health Organization in collaboration with, and subsequently adopted by, the Food and Agriculture Organization of the United Nations and the World Organization for Animal Health;

2. Also reaffirm that the 2030 Agenda for Sustainable Development<sup>2</sup> offers a framework to ensure healthy lives, and commit ourselves to fight malaria, HIV/AIDS, tuberculosis, hepatitis, the Ebola virus disease and other communicable diseases and zoonoses, including by addressing growing antimicrobial resistance and neglected diseases affecting developing countries in particular, while recognizing that antimicrobial resistance challenges the sustainability and effectiveness of the public health response to these and other diseases as well as gains in health and development and the attainment of the 2030 agenda;

3. Acknowledge that the resistance of bacterial, viral, parasitic and fungal microorganisms to antimicrobial medicines that were previously effective for treatment of infections is mainly due to the inappropriate use of antimicrobial medicines in the public health, animal, food, agriculture and aquaculture sectors; lack of access to health services, including to diagnostics and laboratory capacity; and antimicrobial residues in soil, crops and water; within the broader context of antimicrobial resistance, resistance to antibiotics, which are not the only medicines, including vaccines for the treatment of zoonoses, is the greatest and most urgent global risk, requiring increased attention and coherence at the international, national and regional levels;

4. Also acknowledge that, due to antimicrobial resistance, many achievements of the twentieth century are being greatly challenged, in particular the reduction in illness and death from infectious diseases achieved through social and economic development, access to health services, and to quality, safe, efficacious and affordable medicines, vaccines, safe water and sanitation, disease prevention in community and health-care settings, including vaccination, infection and health care, improvements in human and veterinary medicine, and the introduction of new antimicrobial and other medicines;

5. Recognize that the above achievements are now greatly challenged by antimicrobial resistance, including the development of resistant health systems and progress towards the goal of universal health coverage; treatment options for HIV and sexually transmitted infections, tuberculosis and malaria, as well as other infections acquired in community and health-care settings; gains in infection prevention and control in community and health-care settings; advances in

<sup>1</sup> See World Health Organization, Document WHO/CAH/2016.001, annex 3.  
<sup>2</sup> Resolution 70.1.



# IACG | Interagency Coordination Group on **Antimicrobial Resistance**

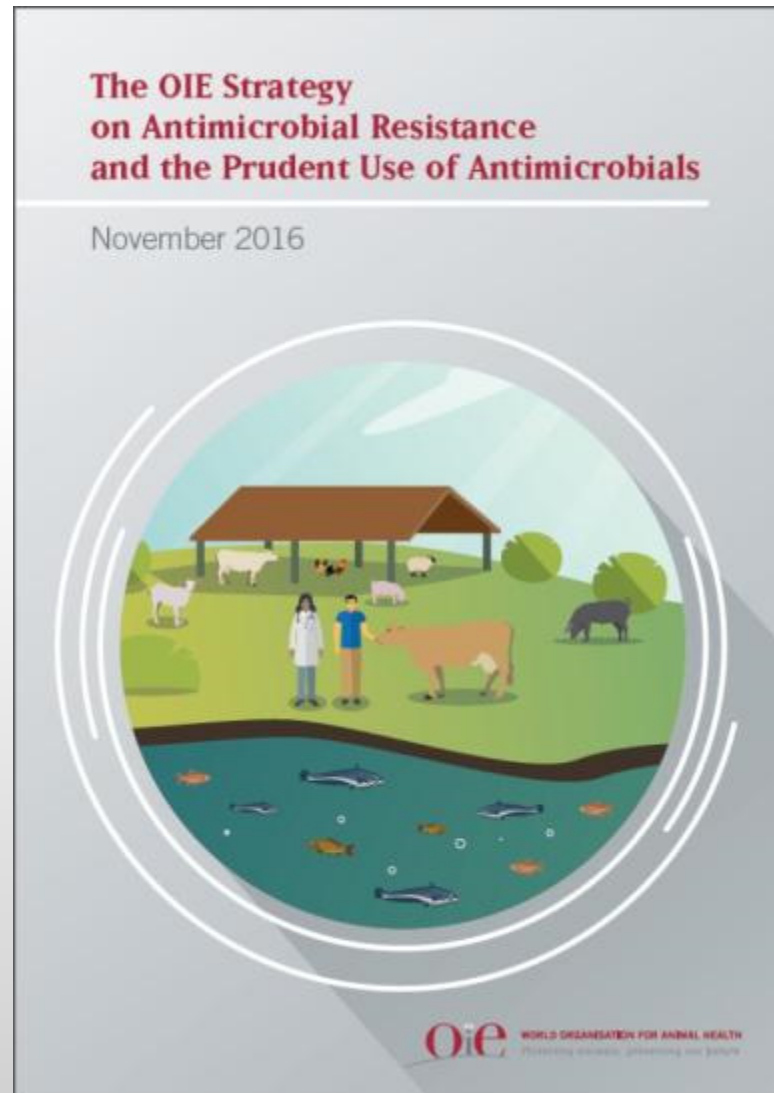
FIRST MEETING OF THE INTERAGENCY COORDINATION GROUP  
ON ANTIMICROBIAL RESISTANCE  
2-3 May 2017, New York

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3 MAY 2017

- **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

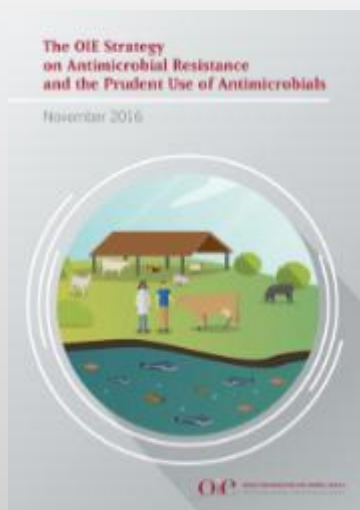


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# The OIE Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials

## 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



International  
for Registr

WHO/FAO Codex Alimentarius  
Commission → MRL

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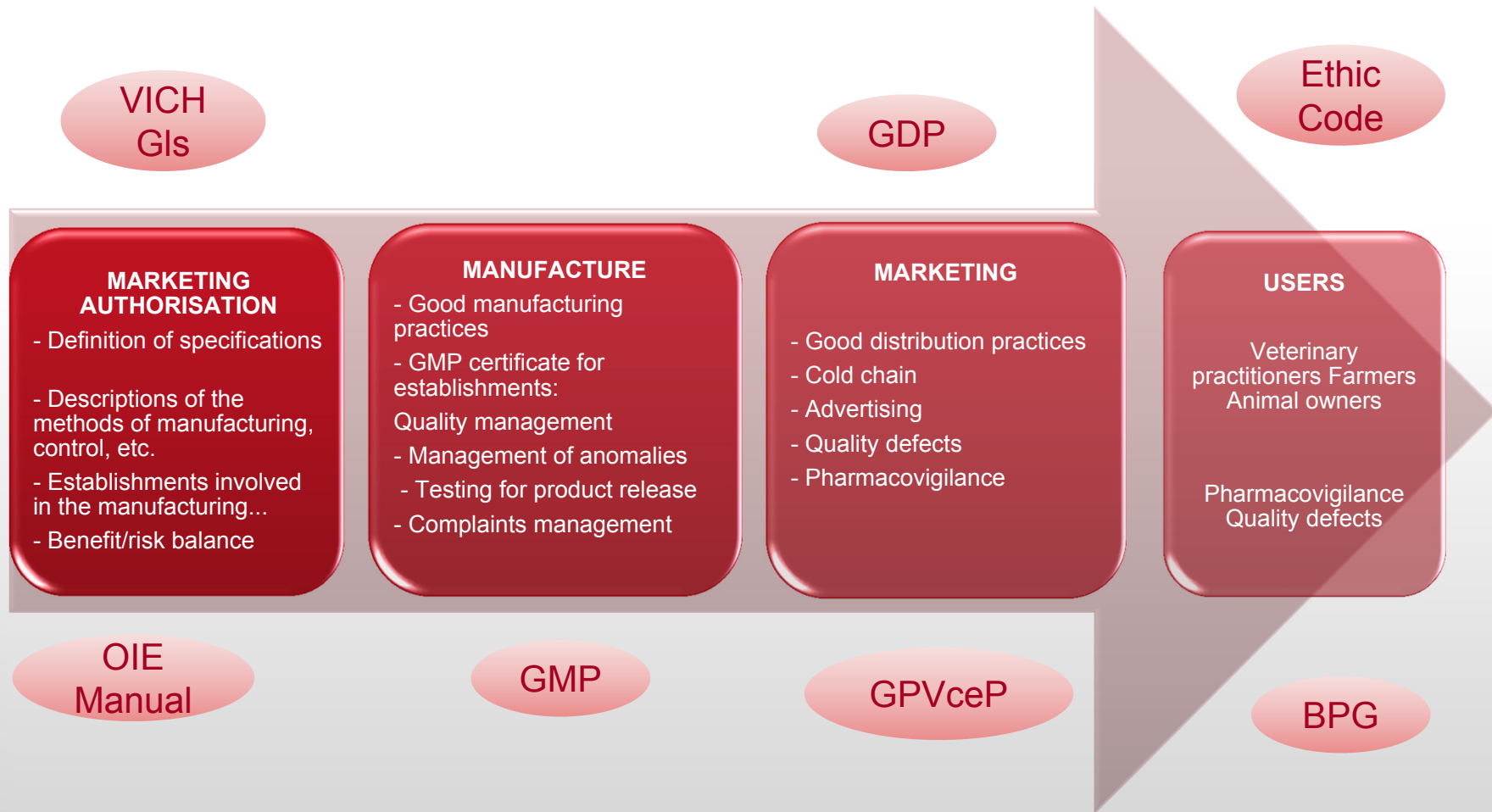
World Organisation for Animal  
Health (manufacturing, quality  
control, AMR...)

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International Cooperation on  
Harmonisation of Technical  
Requirements for Registration of  
Veterinary Medicinal Products



# Good governance for good quality



# 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<sup>th</sup> strategic plan, OIE encourages the use of VICH guidelines;
- Supports the process of setting up the VICH Outreach Forum since the beginning



International Cooperation on Harmonisation of Technical Requirements  
for Registration of Veterinary Medicinal Products

## Goals of VICCH and contribution in One Health Concept

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



International Cooperation on Harmonisation of Technical Requirements  
for Registration of Veterinary Medicinal Products

## 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...



International Cooperation on Harmonisation of Technical Requirements  
for Registration of Veterinary Medicinal Products

## 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



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WORLD ORGANISATION FOR ANIMAL HEALTH  
*Protecting animals, preserving our future*

# Thank you for your attention

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