International approach for veterinary medicinal products: OIE and Codex alimentarius
INTRODUCTION
International approach for veterinary medicinal products: OIE and Codex alimentarius

Benefits
- Animal health and welfare
- Human nutrition
- Economic development

Risks
- Risk for animals
- Risks for humans
- Risks for the environment
OIE/ Codex standards and WTO
Standards-setting organizations

- **food safety**: CODEX
- **animal health**: OIE
- **plant health**: IPPC

Codex = Joint FAO/WHO Codex Alimentarius Commission
OIE = World Organization for Animal Health
IPPC = International Plant Protection Convention (FAO)
Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)

- The SPS Agreement calls on countries to harmonize their national standards with “international standards, guidelines or recommendations” (Article 3.1)
- “international standards, guidelines or recommendations” (Annex A)
  - Codex Standards for food safety
  - OIE for animal health and zoonoses
  - IPPC for plant health

Agreement on Technical Barriers to Trade (TBT Agreement)

- The TBT Agreement calls on countries to use relevant international standards when they exist (Article 2.4).
World Organisation for Animal Health

- an intergovernmental organisation
- founded in 1924 by 28 countries
- created before the U.N.

175 Member Countries

Common name adopted by the International Committee on May 2003
The 6 Objectives of the OIE

ANIMAL HEALTH INFORMATION
- to ensure transparency in the global animal disease and zoonosis situation
- to collect, analyse and disseminate scientific veterinary information

ACTIVITIES OF VETERINARY SERVICES
- to provide expertise and encourage international solidarity in the control of animal diseases
- to improve the legal framework and resources of national Veterinary Services

INTERNATIONAL STANDARD
- to provide a better guarantee of the safety of food of animal origin, and to promote animal welfare, through a science-based approach
- within its WTO mandate, to safeguard world trade by publishing health standards for international trade in animals and animal products
The 4th Strategic Plan:
A new global mandate for 2006/2010

- From prevention of worldspread of animal disease to improvement of Animal health worldwide…

- …with enhanced role in public health, animal welfare and safety of trade policies…

- …including improvement of capacity building
OIE International Standards

- Terrestrial Animal Health Code – mammals, birds and bees
- Aquatic Animal Health Code – fish, molluscs and crustaceans
- Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
- Manual of Diagnostic Tests for Aquatic Animals

available on the OIE Website

http://www.oie.int
Collaborating Centres

Expert Centres on horizontal subjects, for the OIE and Member Countries

- Assist in the elaboration of procedures to harmonise animal disease regulations / international standards
- Coordinate collaborative studies
- Provide technical training
- Organise and host scientific meetings for the OIE
OIE veterinary medicinal products related activities

- 1994
  - « need for initiatives and programmes to foster the harmonisation of registration requirements for veterinary drugs »
  - Resolution N°X, 62nd General Session

- 2001 to 2007
  - OIE antimicrobials and antimicrobial resistance activities (AMR)
2003-2004: Five guidelines adopted and published

- **Terrestrial animal health code (Section 6)**
  - Harmonisation of antimicrobial resistance surveillance and monitoring programmes
  - Monitoring of the quantities of antimicrobials used in animal husbandry
  - Responsible and prudent use of antimicrobial agents in veterinary medicine
  - Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals

- **Manual of Diagnostic Tests and vaccines for Terrestrial Animals**
  - Laboratory methodologies for bacterial antimicrobial susceptibility testing
2006-2007: List of VCIA

“Veterinary critically important important antimicrobial agents”

- Concept drawn after 2 joint FAO-WHO-OIE experts consultation (Geneva 2003, Oslo 2004) on non human antimicrobial usage and antimicrobial resistance

- Exits both in human (WHO) and veterinary (OIE) medicine
The OIE conference on VMPs held in Dakar, Senegal (March 2008) recommends that

- “OIE members promote the control of residues … with standards developed by the Codex Alimentarius …”
- “OIE continue to follow closely the work of VICH and share the results with all the OIE MC”
OIE VMPs related activities

• OIE support to VICH initiative
  ▪ Established under the auspices of the OIE
  ▪ Member of the Steering Committee
A major aim of its 2006-2010 mandate: to ensure the better provision of safe and efficacious VMPs

VMPs are taken into account in all OIE initiatives related to capacity building
Resolution N°25 on veterinary products
77th General Session – May 2009

- Key role of a good governance of VMPs
- Agreed by OIE May 2009 General Assembly to constitute a key element of OIE’s upcoming 5th Strategic plan
OIE Collaborating centre for veterinary medicinal products

- The ANMV is the French Agency for Veterinary Medicinal Products
- Responsibilities in Assessment, Authorisation, Monitoring, Control, Inspections
OIE Collaborating centre for veterinary medicinal products : ANMV

- INTERNATIONAL HARMONISATION
  - OIE (standards; methods; registration of diagnostic assays)
  - Represents OIE for CODEX meeting related to VMP
  - Participates to WHO/FAO/OIE workshop, expert groups on VMP
  - Represents OIE to VICH

- RESEARCH and EXPERTISE
  - Antimicrobial resistance, Benefit/Risk Assessment
  - Pharmaceutical regulation

- TECHNICAL ASSISTANCE
  - Bilateral and multilateral cooperation and assistance to OIE member countries (especially developing countries)
  - Twinning
Codex Alimentarius APPROACH
• Intergovernmental body
• Status adopted in May, 1963
• Created by FAO and WHO

CODEX alimentarius

Collection of food standards, guidelines and codes of practice

Latin for “food code”
To protect the health of consumers
To ensure fair practices in international food trade
To coordinate all food standardisation work done by international organisations
Activities focussed on main risks linked with the use of VMP
Codex Committee on Residues of Veterinary Drugs in Foods

- to determine priorities for the consideration of residues of veterinary drugs in foods
- to recommend maximum levels of such substances (MRL)
- to develop codes of practice
- to consider methods of sampling and analysis for the determination of veterinary drug residues in foods
- CCRVDF develop standards based on evaluations by JECFA
JECFA RISK ASSESSMENT

- International expert scientific committee

- Evaluate food additives (more than 1500), contaminants, naturally occurring toxicants and residues of veterinary drugs in food (approximately 90 veterinary drugs)

- JECFA advice on residues of veterinary drugs to the CCRVDF:
  (i) elaborates principles for evaluating their safety and for quantifying their risks;
  (ii) establishes ADIs and other guidance values for acute exposure
  (iii) recommends maximum residue limits (MRLs) for target tissues; and
  (iv) determines appropriate criteria for and evaluates methods of analysis for detecting and/or quantifying residues in food.
Collaboration between OIE and Codex *Alimentarius*
Collaboration between OIE and Codex alimentarius

- No formal agreement with Codex
- Separate Agreement between OIE and FAO and OIE and WHO (2004)
- Current Status of OIE in Codex: Observer
The 1st Session of the Ad Hoc Codex Intergovernmental Task Force on Antimicrobial Resistance

October 23 (Tue) - 26 (Fri), 2007
Imperial Palace Hotel, Seoul, Korea

Objective

To develop science based guidance, taking full account of its risk analysis principles and the work and standards of other relevant international Organizations, such as FAO, WHO and OIE. The intent of this guidance is to assess the risks to human health associated with the presence in food and feed including aquaculture and the transmission through food and feed of antimicrobial resistant microorganisms and antimicrobial resistance genes and to develop appropriate risk management advice based on that assessment to reduce such risk.

Terms of reference

To develop guidance on methodology and processes for risk assessment, its application to the antimicrobials used in human and veterinary medicine as provided by FAO/WHO through JEMPA, and in close cooperation with OIE, with subsequent consideration of risk management options. In this process, work undertaken in this field at national, regional and international levels should be taken into account.

Time frame

The Task Force shall complete its work within four sessions, starting 2007.
3 meetings since 2007

Development of scientific standards

Reflect the basic principles of risk analysis issued by other international organisations such as OIE, FAO and WHO
CONCLUSION
Conclusion

- International standards are useful tools for countries to be used
  - Public health
  - International trade

- OIE cooperates actively with Codex in the field of Veterinary medicine particularly in CCRVDF and in Codex Task force on antimicrobial resistance