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Introduction to the working sessions

Need for a good governance regarding Veterinary Medicinal Products

Workshop for OIE national Focal Points for Veterinary Products
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Introduction

- For economic and health impact reasons,
  - sound pharmaceutical policies and regulations,
  - minimum quality standards for drugs,
  - transparent licensing, registration and distribution
  - and evidence-based prescription practices
- are essential for both consumers and policy makers

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Introduction

- Factors that increase system's susceptibility to mismanagement, fraud and corruption:
  - Wide discretion,
  - lack of transparency in decision making
  - lack of accountability for decisions

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Introduction

- Veterinary Medicinal Products (VMPs):
  - Veterinary tools, contributing to the improvement of animal and public health worldwide, and of economical development
- The VMP policy as part of the animal health policy

Need for a robust legislative and regulatory framework implemented and a strong and comprehensive governance linked to national veterinary services

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Content

- A comprehensive set of legislative and regulatory requirements
- How to improve Governance regarding Veterinary Medicinal Products?

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Legislative and regulatory requirements

- Public policy
- Activities to be covered
- Institutional organization
- Penalties and administrative action

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Legislative and regulatory requirements

- Public policy
  - A strong commitment to ensure efficiency, competence and impartiality
- Activities to be covered
- Institutional organization
- Penalties and administrative action

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Legislative and regulatory requirements

- Public policy
- Activities to be covered
  - All activities along the entire life of VMPs from development to usage, including residues aspects
- Institutional organization
- Penalties and administrative action

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Activities to be covered
(All, from manufacturing to usage)

- **Manufacturing**
  - Good Manufacturing Practice (GMP)
  - inspections to assure GMP compliance…
- **Registration**
  - Establish transparent, effective laws and standards for drug registratio
  - Regulate imports, clinical trials
  - Maximum residue limits setting
  - Implement market surveillance Pharmacovigilance, advertising
  - Ensure transparency …
- **Control**
  - Of Veterinary medicinal products
  - Of residues
- **Distribution**
  - Regulate allocation, transport, and storage of drugs
  - Secure appropriate storage facilities and transport…
- **Use:**
  - Develop and engage professional associations to improve adherence to professional codes of conduct.
  - Impose penalties for breaches of legal and ethical standards.
  - Regulate industry interaction with prescribers…

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Legislative and regulatory requirements

- Public policy
- Activities to be covered
- Institutional organization
  - Scope of responsibilities and mission statement
  - Science based decision making process
  - Human resources
  - Fee system
  - Transparency and communication responsibilities
- Penalties and administrative action

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Legislative and regulatory requirements

- Public policy
- Activities to be covered
- Institutional organization
- Penalties and administrative action
  - Administrative capacities of NCAs
  - Prosecution capacities
  - Coordination among official services
  - Transparency and communication

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How to improve Governance regarding Veterinary Medicnal Products?

- Establish a Diagnostic of the system First !!!

Then

Take actions.

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OIE-PVS can Help

Section II-9 Veterinary medicines and veterinary biologicals

Veterinary medicines and veterinary biologicals	Levels of advancement	Suggested indicators
The authority and capability of the VS to regulate veterinary medicines and veterinary biologicals.	1. The VS cannot regulate the usage of veterinary medicines and veterinary biologicals.	
	2. The VS has only limited capability to exercise administrative control (including registration) over the usage, including import and production, of veterinary medicines and veterinary biologicals.	•Documented administrative process, including for setting fee-for-service •Registration dossiers for import and production •Records on performance of these functions
	3. The VS exercise quality control (technical standards) over the import, production and distribution of veterinary medicines and veterinary biologicals.	•Documented quality control procedures and results of controls •Information on adverse findings and action taken •Dedicated staff and/or equipment
	4. The VS exercise complete control over registration, sale and usage of veterinary medicines and veterinary biologicals.	•Documented procedures for and evidence in regard to the collection of samples, including results, and decision making in response to findings
	5. The VS implement systems to monitor the use of veterinary medicines, veterinary biologicals and their side effects (pharmacovigilance).	**•Legislation and procedures for the control of VM and VB distribution •Evidence of the systematic collection of relevant information and decisions in response to findings**

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Example of more precise tools

BEMA (Benchmarking of Medicines Agencies)

Key issues:

- ***management***
- ***scientific and technical assessment***
- ***inpection and laboratory control***
- ***surveillance (pharmacovigilance; residue control)***

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Efficiency of the legislation : need of benchmarking

- Key issues:

-management

  - *Governing principles*
  - *Relationship with stakeholders*
  - *Risk management policy*

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Efficiency of the legislation : need of benchmarking

- Key issues:

-scientific and technical assessment

  - *Resources*
  - *Competences*
  - *Opinion making process*
  - *Coordination with inspection and pharmacovigilance*

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Efficiency of the legislation : need of benchmarking

- Key issues:

-inpection and laboratory control

  - *Competences and resources*
  - *Existing good practices*
  - *Laboratory control*
  - *Rapid alert system and batch recall (tracaebility)*
  - *Follow up of inspections and controls*
  - *Coordination of official services*

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Efficiency of the legislation : need of benchmarking

- Key issues:

-surveillance (pharmacovigilance; residue control)

  - *Data collection*
  - *Monitoring and control plans for residues*
  - *Coordination of official services*
  - *Resources*

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CONCLUSION

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How to succeed?

- **Involvement of veterinary services, VMPs being part of their duties**
- **Information, Training, Communication**
- **Transparency with all the stakeholders and the public**

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Efficiency of the legislation: need of a favourable environment

- Regional networking
- OIE support to international cooperation:
  - strengthening Veterinary Services
  - development of twinnings

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Conclusion

- **Considering the impact of VMPs in the global animal health policy, the market globalisation and the limited resources, the way forward implies:**
  - ***A strong political commitment***
  - ***A proportionate and targeted action***
  - ***A networking and work sharing approach and when possible a regional approach***
  - ***Transparency and relationships among stakeholders***

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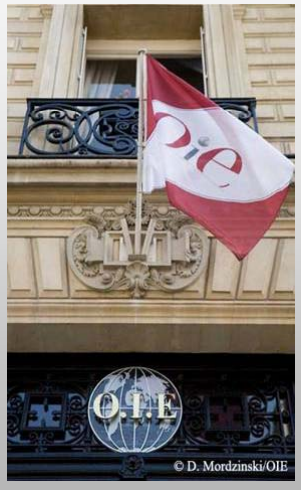
Thank you for your attention



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BACKGROUND SLIDES

Key Performance Indicators of BEMA project

- **KPI 1: Describe how objectives or targets are set for the different processes of the organisation, and they are reported publicly**
- **KPI 2: Describe how the organisation identifies different stakeholders' (other regulatory bodies, patients/public, healthcare professionals, animal owners, vets and consumers and industry) needs and expectations on a continual basis.**
- **KPI 3: Documented systems are in place to ensure that risks to the functions, finance, reputation and business processes of the NCA are identified and effectively managed. (internal risk management).**

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Key Performance Indicators of BEMA project

- **KPI 4: Appropriate measures are in place to protect confidential information from security threats, maintain the physical security of buildings and property and to protect staff.**
- **KPI 5: The capability and capacity of performing pre- and post-authorisation activities with high quality is demonstrated.**

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Key Performance Indicators of BEMA project

- **KPI 6: The full range of high-level, internationally recognised, regulatory and scientific expertise to fulfil the chosen regulatory functions is available within the organisation and from appropriate external sources.**
- **KPI 7: The organisation has the capacity to receive, validate, use and archive fully electronic applications and data submissions using robust modern information management systems.**
- **KPI 8: There is routine access to reliable systems for use in signal detection/evaluation, preferably in house.**

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Key Performance Indicators of BEMA project

- **KPI 9: The organisation has the ability to produce consistently high quality risk pharmacovigilance assessments to deadlines.**
- **KPI 10: The organisation has the capability of leading EU wide co-ordination of regulatory action and communication of drug safety issues.**
- **KPI 11: There are appropriate GXP standards in place and compliance with these is monitored and enforced**
- **KPI 12: There is a documented system for ensuring the removal of non-compliant medicinal products from the market**

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