Ministry of Agriculture, Forestry and Water Management

Veterinary Directorate

Serbian experience in setting up EU compatible Veterinary Medicine Products registration system

Dr Budimir PLAIVIC,
Head of Animal Health Department
OIE VMP Focal Point

Workshop for OIE National Focal Points for Veterinary Medicine Products
Vienna, Austria, 20-22 Nov 2012
Veterinary Medicine Products

Topics:
- Organizational diagram (VMP)
- Legal framework
- Historical overview
- Competent authorities
- Roles and responsibilities
- Successful story of harmonization of VMP system (2004-2012)
National authorities (VMP)

According to national Law in the field of medicines for veterinary use in Serbia two institutions are responsible:

♦ Ministry of Agriculture, Forestry and Water Management - Veterinary Directorate

♦ Agency for medicines and medical devices.
ORGANIZATIONAL DIAGRAM - VMP

The Government

M o A

Veterinary directorate

M o H

Agency for medicine and medical devices

Approval

Inspection & Audit

Veterinary pharmacies

Wholesale of VMP

Production of VMP

Licensing of medicines and medical devices
VMP in Serbia - Legal base

- Significant efforts to improve legislative for VMP (transposition of EU legislative, harmonization with OIE standards)
- Multi-sectorial approach
- Consultation with interested parties
- VMP legislative body:
  - Law on veterinary matters
  - Law on medicines and medical devices
  - Rule book on minimal requirements for veterinary pharmacies
  - Rule book on minimal requirements for medicine production
  - Rule book on minimal requirements for wholesale of medicines and medical devices
  - Guidelines on Good Manufacturing Practice
  - Guidelines on Good Laboratory Practice
  - Guidelines on Good Practice in distribution of medicine and medicine devices
Competences:

- Animal health, welfare and traceability
- Veterinary Public Health and Food Safety
- Protection and improvement of environment and nature
REPUBLIC OF SERBIA
MINISTRY OF AGRICULTURE, FORESTRY AND WATER MANAGEMENT

VETERINARY DIRECTORATE
Director – Chief Veterinary Officer - CVO

ASSISTANT

DEPARTMENT FOR INTERNATIONAL TRADE AND CERTIFICATION
HEAD OF DEPT.

DEPARTMENT FOR BORDER VETERINARY INSPECTION
HEAD OF DEPT.

DEPARTMENT FOR VETERINARY INSPECTION
HEAD OF DEPT.

GROUP FOR LEGAL AND GENERAL AFFAIRS
CHIEF OF THE GROUP

GROUP FOR INTERNAL AUDITS & QMS
CHIEF OF THE GROUP

DEPARTMENT FOR VETERINARY PUBLIC HEALTH
HEAD OF DEPT.

GROUP FOR FINANCE & ADMINISTRATION
CHIEF OF THE GROUP

DEPARTMENT FOR ANIMAL HEALTH & WELFARE
HEAD OF DEPT.

GROUP FOR EPIZOOTIOLOGY AND ANIMAL WELFARE
CHIEF OF THE GROUP

UNIT FOR VETERINARY SERVICES
CHIEF OF THE UNIT

UNIT FOR INTERNATIONAL TRADE
CHIEF OF THE UNIT

GROUP FOR CERTIFICATION & VETERINARY AND SANITARY MEASURES
CHIEF OF THE GROUP

REGIONAL BORDER INSPECTION STATIONS
4 – UNITS & 3 - GROUPS

BORDER INSPECTION POSTS
(BIPs)/ VET. INSPECTORS

INSPECTION GROUP FOR ANIMAL HEALTH & ANIMAL WELFARE
CHIEF OF THE GROUP

INSPECTION GROUP FOR FOOD SAFETY & QUALITY & ABPs
CHIEF OF THE GROUP

INSPECTION GROUP FOR EXPORT ESTABLISHMENTS
CHIEF OF THE GROUP

INSPECTION GROUP FOR PRODUCTION AND TRADE CONTROL OF VET DRUGS & FOR FEED
CHIEF OF THE GROUP

UNIT FOR REGISTRATION & APPROVAL OF ESTs FOR FOOD, FEED & ABPs
CHIEF OF THE UNIT

GROUP FOR FOOD SAFETY SYSTEMS
CHIEF OF THE GROUP

UNIT FOR EPIZOOTIOLOGY AND ANIMAL WELFARE
CHIEF OF THE UNIT

GROUP FOR ID&R OF ANIMALS
CHIEF OF THE GROUP

UNIT FOR INTERNATIONAL TRADE
CHIEF OF THE UNIT

UNIT FOR EPIZOOTIOLOGY & TECHNOLOGY
CHIEF OF THE UNIT

VETERINARY INSTITUTES/LABS:
- ANIMAL HEALTH
- FOOD SAFETY
- INSTITUTE OF MEAT HYGIENE & TECHNOLOGY:
- RESIDUE MONITORING

VETERINARY STATIONS
(VETERINARY PRACTICE)

DISTRICT VETERINARY INSPECTION OFFICES
25 - CHIEFS OF THE UNITS
<table>
<thead>
<tr>
<th>Personnel</th>
<th>Veterinary Staff</th>
<th>Administrative Staff</th>
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<tr>
<td>CENTRAL ADMINISTRATION</td>
<td>48</td>
<td>10</td>
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<tr>
<td>Vet. Inspection Central Level</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>Vet. Inspection District Level</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Vet. Inspection Local Level</td>
<td>322</td>
<td>-</td>
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<tr>
<td>Border Vet. Inspection</td>
<td>31</td>
<td>-</td>
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</table>
Licensing system and competence

Veterinary Directorate is responsible for:

a) **Approval of:**
   - Manufacturers of veterinary medicines.
   - Wholesale distribution of medicinal products,
   - Pharmacies,
   - Contract laboratories,
   - Manufacturers and importers of active pharmaceutical ingredients.

b) **Official control, inspection and audit**
GMP standard

- Law on Medicines and Medical Devices
- Rulebook on conditions for medicines manufacturing
- Guidelines to Good Manufacturing Practice in compliance with directive 91/412 / EEC.
Inspection and audit

a) According to Law, paragraph 209, requirement qualifications for inspectors are:
   ♦ university degree (Faculty of veterinary medicine)
   ♦ 3 years of relevant professional experience
   ♦ knowledge of legislation in field of medicines and medical devices, rights and duties of inspectors, knowledge of certain legal regulations.

b) Number of inspectors:
   ♦ four inspectors are employed on full time bases, also dedicated to GMP/GDP inspection and other inspections under their jurisdiction.
c) Training program:

- Inspectors are formally qualified once when successfully passed examination for work in ministry.
- New inspectors for first six months - theoretically and practical training
- Regular training program and continuous education
Format and content of inspection reports

Official report contains:
♦ Report number and date of inspection;
♦ Name of inspector(s);
♦ Name and address of inspected company, place of inspection;
♦ Purpose and scope of inspection;
♦ Reference to inspection;
♦ Names of responsible persons met during the inspection;
♦ Date, scope and findings of previous inspection,
♦ Description of activities during the inspection,
♦ Inspector’s findings and observations,
♦ Conclusion with recommendations that have to be carry out,
♦ Signature(s) of inspectors(s) and signature(s) of responsible person(s).
In accordance with the Law inspector takes a measures, if it is necessary.
Procedures

• SOP for conducting inspections and post inspection activities
• Non-compliance management
• Written decision for corrective action
• In the case of serious non-compliance inspector has an obligation and duty to:
  ♦ temporarily suspend manufacturing, testing, marketing of medicinal products until the problem is resolved,
  ♦ other measures according to the Law.
Medicines and Medical Devices
Agency of Serbia (ALIMS)

ALIMS has officially been established to operate from 1st October 2004 in compliance with the new reformative Law on Medicines and Medical Devices
According to the Law on Medicines and Medical Devices (Official Gazette of Republic of Serbia, No 30/2010) Agency is competent for:

**PRE marketing procedures**
- quality, safety, efficacy documentation assessment and QC of medicines
- Clinical trials documentation assessment
- GCP control

**POST marketing procedures**
- Laboratory quality control
- Pharmacovigilance
- Information
- Medicines and medical devices consumption
- Pharmacoeconomy
- Pharmacoepidemiology
Veterinary Medicines Department

- Formal completeness assessment
- Veterinary Medicines Documentation Assessment
- Clinical Trials
- Pharmacovigilance
- Product classification
Veterinary Medicines Department mission

OF VETERINARY MEDICINES
IN SERVICE OF:

QUALITY

SAFETY

EFFICACY

PUBLIC HEALTH PROTECTION

ANIMAL HEALTH AND WELFARE

ENVIRONMENT PROTECTION
Veterinary Medicines Department activities

PRE-MARKETING ACTIVITIES

CLINICAL TRIALS DOCUMENTATION ASSESSMENT
CLINICAL TRIALS MONITORING

VETERINARY MEDICINES DOCUMENTATION ASSESSMENT

POST-MARKETING ACTIVITIES

PHARMACOVIGILANCE
POST-MARKETING STUDIES
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<th>CLINICAL TRIALS MONITORING</th>
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<td>Organization of Committee for clinical trials approval of VMs</td>
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<td>Clinical trials monitoring</td>
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<td>Certificates on implementation of GCP guidelines</td>
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<td>Cooperation on efficacy documentation assessment</td>
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advisory body: Committee for clinical trials approval
Processing, assessing and reporting to Committee for VM on:

ADMINISTRATIVE DOCUMENTATION
QUALITY DOCUMENTATION
DOCUMENTATION ON SAFETY AND RESIDUES
DOCUMENTATION ON EFFICACY

In procedures of:

MARKETING AUTHORIZATIONS
RENEWALS
VARIATIONS

Opinions for approval certificates of unauthorized VMs import

number of independent experts: 27
advisory body: Committee for veterinary medicines
PHARMACOVIGILANCE

Marketed medicines monitoring and information collecting

Adverse drug reactions identification and monitoring

Post-marketing studies on undesirable effects

Collaboration with Pharmacovigilance NC and experts

Cooperation on safety documentation assessment

POSTMARKETING STUDIES

advisory body: Committee for pharmacovigilance of VMs
Veterinary Medicines Department Procedure

Application admittance

Formal completeness ass. 60 days

LoD 30 days to complete

Documentation assessment 210 days

Clock-stop 180 days for additional documentation

Committee for veterinary medicines

Conditional requests

Marketing Authorization or Refusal
Official Medicines Control Laboratory

National Control Laboratory is in integral part of Agency for medicines and medical devices.

♦ **Accredited against ISO 9001 and ISO:14001**

♦ **Full-fledged member of the Official Medicines Control Laboratories (OMCL) Network**
National Control Laboratory performs quality control of medicines:

- During the authorization process,
- First batch release,
- Each batch manufactured in Serbia - vaccines, serums, toxins, allergens, medicines from the blood,
- Systematic control of the medicines sampled from market - taking random samples,
- Imported medicine,
- Sampled medicines with suspected quality.
Consumer is able to complain on expected quality of medicine.
Inspectors make plan of action for determination reasons of complain.
Agency may recommend to the Veterinary Directorate to carry out inspections or audit
Conclusion:

Common goal: Product with satisfactory quality, efficacy and safety

 Necessary: Harmonization with EU regulations

Product on the market: Continuous process:
- Harmonization with EU regulations
- Reporting every change related to the product (variation)
Thank you for your kind attention