Ministry of Agriculture, Forestry and Water Management
Veterinary Directorate

Veterinary Medicine Products

Dr Budimir PLAVSIC, Head of Animal Health Dpt.

Workshop for OIE National Focal Points for Veterinary Products
Belgrade, Serbia, 26-28 July 2010
Competences

- Animal health
- Veterinary Public Health and Food Safety
- Animal welfare
- Protection and improvement of environment and nature
Veterinary Directorate

Improvement of veterinary service:

1. **Human and financial resources**
   - Professional and technical competence
   - Continuing education
   - Technical independence and stability of programmes
   - Funding/investment/development

2. **Technical authority and capability in the field of animal health/welfare and veterinary public health**
   - Field activities (animal control programmes)
   - Laboratory diseases investigations
   - Quarantine and border security
   - Epidemiological surveillance
   - Early warning/detection and emergency response
   - Contingency planning and implementation

3. **Interaction with stakeholders (Coordination and communication)**

4. **Access to markets with healthy animals and safe food of animal origin**
   - Approximation/harmonization and implementation of (EU) regulations
   - International harmonization/certification
   - Equivalence in sanitary issues
   - Transparency
Veterinary Directorate

Director (CVO)

A. Management of VD and internal Departments:

1. Animal Health, Welfare and Traceability
2. Veterinary Public Health
3. International Trade & Certification
4. Veterinary Organization and Services Registration
5. Veterinary Inspection Service
6. Veterinary Border Inspection
7. Unit for audit and Quality Management
8. Legal & General Affairs
9. Finance & Administration
VETERINARY DIRECTORATE

Roles and responsibilities:

**Animal Health, Welfare and Traceability**
- Animal Health Control - Annual Animal Health Programmes
- Animal Diseases Notification
- Animal Welfare
- Animal I&R

**Veterinary Information Management System**
- Animal Identification & Registration (I&R),
- Holding registration,
- Animal movement,
- Registration of Ests/Farms,
- Laboratory information system (L.I.M.S.),
- Document Management.
VETERINARY DIRECTORATE

Roles and responsibilities:

**Veterinary Public Health**
- Approval of ESTs (food of animal origin, feed, animal-by products),
- National Residue Monitoring Programme,
- Food&Feed&ABPs Safety and Control Systems,
- Training and education.

**Veterinary Services**
- Registration and approval of VMP factories, wholesales and pharmacies,
- Registration and approval of Vet Organisations (labs and vet practices),
- Authorization of Labs,
- Authorization of Vets for specific vet inspection activities,
- Authorization of Vet practices for implementation of National Disease Control Programs
VETERINARY DIRECTORATE

Roles and responsibilities:

**International Trade & Certification**

- Veterinary Import conditions,
- Veterinary Health Certificates,
- International cooperation,
- Training coordination and Training Data Base,

**Border Inspection**

- Documentation checks
- Physical checks
- Laboratory checks
VETERINARY DIRECTORATE

Roles and responsibilities:

**Veterinary Inspection Service**

- Animal Health,
- Animal Welfare,
- Food Safety – ESTs and Internal Control Systems,
- Feed Safety - ESTs and Internal Control Systems,
- Veterinary Medicinal Products

**Unit for audit and Quality Management**

- Initial phase of development
- Trainings of Staff – In progress
<table>
<thead>
<tr>
<th>Personnel</th>
<th>Veterinary Staff</th>
<th>Administrative Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>CENTRAL ADMINISTRATION</td>
<td>48</td>
<td>10</td>
</tr>
<tr>
<td>Vet. Inspection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central Level</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>District Level</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Local Level</td>
<td>322</td>
<td>-</td>
</tr>
<tr>
<td>Border</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Vet. Inspection</td>
<td>31</td>
<td>-</td>
</tr>
</tbody>
</table>
ORGANIZATIONAL DIAGRAM - VMP

The Government

MoA

Veterinary directorate

Approval

Veterinary pharmacies

Wholesale of VMP

Production of VMP

Inspection & Audit

inspection

audit

Agency for medicine and medical devices

MoH

Approval

Licensing of medicines and medical devices
DEPARTMENT FOR VETERINARY SERVICE

- Veterinary medicines production
- Approval of veterinary drug factories and trade of veterinary medicine-control system and audit

LEGAL BASE:
- Law on veterinary matters (Veterinary framework act)
- 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
Establishing of minimal requirements and issuing of approval

- Formal application with required documents
- Checking of documents, blueprints, procedures and protocols for medicine production, staff ...
- Appointment of technical commission
  - (Department for veterinary inspection service, Unit for inspection of medicine production and trade of medicine and medical devices)
- Inspection and checking of facility
  - (issuing of the official records and technical opinion, opinion of technical commission is relevant for issuing of approval)
- Registration of applicants as a legal person in Serbian Business Register Agency
- Issuing of approval (signed by CVO)
Application for approval of production of medicines and medical devices

- Application form
  - (formal information: name, addressee, type of production etc.)
- The list of medicines and medical devices which planned to be produce
  - (type, form, active materials and brief explanation of manufacturing processes)
- Blueprints of facilities:
- Procedures and protocols of medicines and medical devices production in regard technical information, information about GMP, etc;
- Relevant Information about possible impact on nature (Ministry for Environmental Protection or Municipality Department for Environmental Protection depends on the type and scope of production)
- Information about staff and training of staff (qualifications and diplomas)
- Taxes
Application for registration and approval of veterinary pharmacies wholesales

- Application form (formal information: name, addressee, type of production etc.)
- The list of medicines and medical devices which planed to be sale (type, form and classification);
- Blueprints of facilities:
- Procedures and protocols in regard to GDP and other stipulated prerequisites etc;
- Information about staff and training of staff (qualifications and diplomas)
- Taxes
Thank you for your kind attention