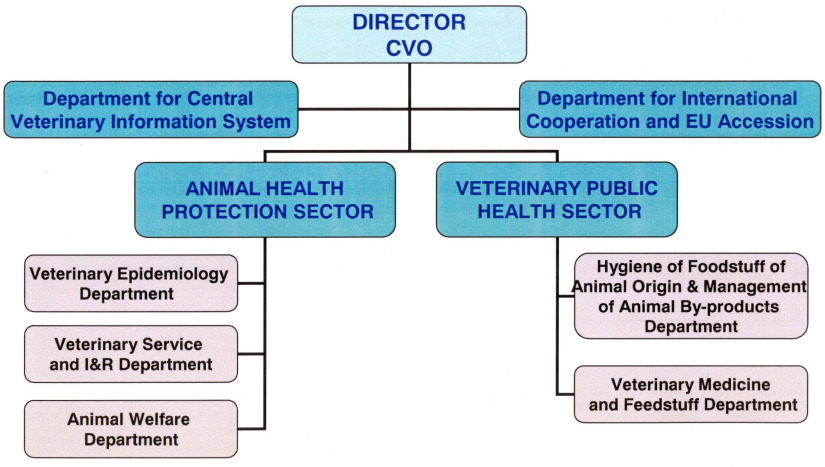
VETERINARY MEDICINAL PRODUCTS IN CROATIA

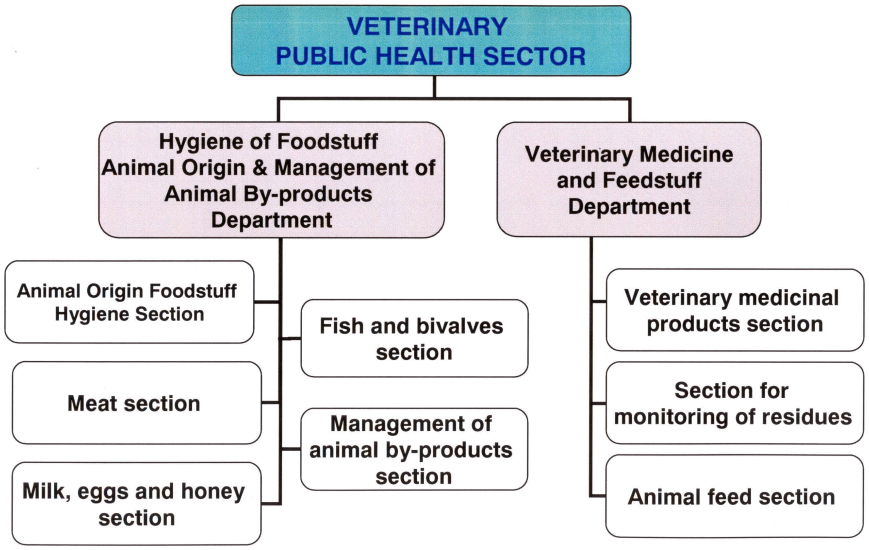
Ministry of Agriculture, Fisheries and Rural Development
Veterinary Directorate

Presented by: Sanja Šeparovic
Veterinary Directorate, Director, CVO

VETERINARY DIRECTORATE



VETERINARY PUBLIC HEALTH SECTOR



AUTHORISATION OF VMP
Competences

1/2

MINISTRY OF AGRICULTURE, FISHERIES AND RURAL DEVELOPMENT - national competent authority

- Committee for VMP (members appointed from the Minister)
- granting marketing authorisation of VMP - valid for 5 years
- Keeps the Register of VMP
- Authorised VMP published in Official Gazette, web (**www.mps.hr**).

AUTHORISATION OF VMP
Competences

CROATIAN VETERINARY INSTITUTE

- Laboratory for analysis of VMP, Zagreb,
  - Quality control of VMP
  - assessment reports for marketing authorisation of VMP.

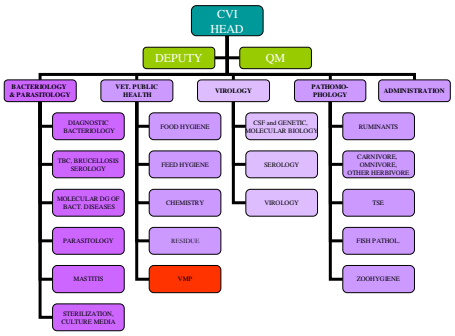
VETERINARY FACULTY

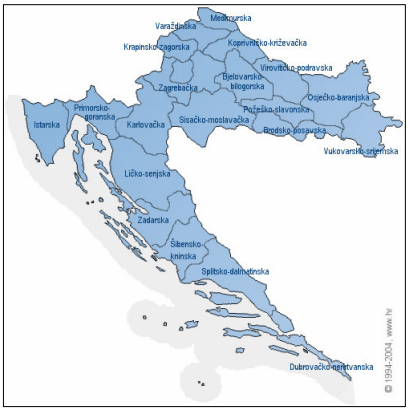
- pharmaco – toxicological assessment reports

CROATIAN VETERINARY INSTITUTE

- Established in 1933
- Public institution, owned by the State, which position and activities are regulated by several laws
- Responsible to:
  - Ministry of Agriculture, Fisheries and Rural Development
  - Ministry of Science, Education and Sports
  - In collaboration with the Ministry of Health and Social Welfare

CROATIAN VETERINARY INSTITUTE Zagreb has
5 regional branches
244 employees



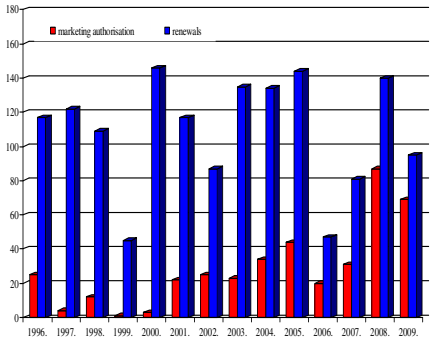


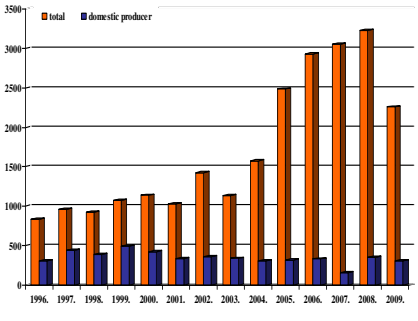
CROATIAN VETERINARY INSTITUTE
Veterinary medicinal products

ASSESSMENT REPORTS

according to **national procedure**

QUALITY CONTROL OF VMP





Level of implementation of the *acquis*

1/2

1. Act on veterinary medicinal products, **Directive 2001/82/EC** of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products and amendments as modified by Directive 2004/28/EC,

2. Ordinance on veterinary medicinal products, **Directive 2001/82/EC** of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products and amendments as modified by Directive 2004/28/EC,

3. Ordinance establishing principles and guidelines of good manufacturing practice for veterinary medical products, **Commission Directive 91/412/EEC** of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products

4. Ordinance on veterinary medical products dispensing without veterinary prescription intended for human consumption. **Commission Directive 2006/130/EC** of 11 December 2006, Implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription

Level of implementation of the *acquis*

2/2

5. Ordinance on list of active substances essential for the treatment of equidae, **Commission Regulation (EC) No 1950/2006** of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae,

6. Ordinance on good laboratory practice (GLP) and verification of application of the principles of good laboratory practice for tests on veterinary medicinal products, **Directive 2004/10/EC** of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of GLP (good laboratory practice) and the verification of their applications for tests on chemical substances,

7. Ordinance on pharmacovigilance for veterinary medicinal products, **Commission Regulation (EC) No 540/95**, of 10 March 1995, laying down the arrangements for reporting suspected unexpected adverse reactions which are not serious, whether arising in the Community or in a third country, to medicinal products for human or veterinary use authorized in accordance with the provisions of Council Regulation (EEC) No 2309/93

National legislation

1. Ordinance on the prescription and dispensing of veterinary medicinal products
2. Ordinance on conditions regarding retail sale and wholesale of proprietary medicinal products, medicinal additives and veterinary medical products carrying out by legal or natural persons
3. Ordinance establishing principles of quality control of proprietary medicinal products, medicinal additives and veterinary medical products and of manner of keeping records
4. Ordinance establishing manner and principles issuing marketing authorisation for proprietary medicinal products, medicinal additives and veterinary medical products
5. Ordinance on advertising of veterinary medical products

Remains for transposition in 2010

Directive 2009/53/EC

Directive 2009/9/EC

Regulation (EC) No 470/2009

Regulation (EC) No 1234/2008

Veterinary Pharmaceutical Industry

- Industry development
  - One national producer of VMP
- Products that are licensed / imported
  - 600 VMP authorised in Croatia

Pharmacovigilance, Inspection, Authorisation

- Pharmacovigilance
  - Prescribed by VMP Act, Ordinance
- Inspection
  - State veterinary inspectors, Veterinary Inspection Directorate, MAFRD
- Authorisation of the medicines
  - Competent Authority – MAFRD
  - Other institutiones involved

Challenges, solutions, outcomes, goals

- Participating at EMEA meetings, working parties
- Finalization of the proces of Accreditation ISO 17025 - CVI
- Interlaboratory colaboration (EDQM, OMCL)
- Education in EU agencies
- Continuation of Acquis transposition into national legislation
- Strenghthening of the administrative capacities
- Improvement of information transparency and availability

Thank you for your attention