



FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org

**Challenges for Candidate Countries:
implementing the
Veterinary Medicines Legislation**

Zagreb, 18 March 2008
TAIEX, AGR 26438

1



FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org

Overview

**Veterinary Medicines
Legislation in the
EUROPEAN UNION**

Nancy De Briyne DVM
FVE Dep Exec Director

2



FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org

What I will talk about:

- * Vet Med Directive (2001/82/EC)
- * EMEA & CVMP
- *MRL Regulation (2377/90)

3



FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org

**VET MED DIRECTIVE
Directive 2001/82/EC**
(revised by Dir 2004/28/EC)

4



FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org

VET MED Directive

- * Definition & Scope
- * Marketing
- * Possession, distribution and dispensing
- * Advertising

5



FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org

**DEFINITIONS & SCOPE
(art 1-4)**

- Veterinary Medicinal Product
- Veterinary Prescription
- Scope

6

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org

Chapter I: Marketing authorisation (art 5-15)
Chapter II: Homeopathic veterinary Medicines (art 16-20)
Chapter III: Procedure Marketing authorisation (art 21-30)
Chapter IV: Mutual recognition & decentralised procedure (art 31-43)
Title IV: Import and Manufacturing
Title V: Labelling and Package Insert
Title VI: Possession, distribution and dispensing (art 65-71)

7

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org

MARKETING (Art 5-15)

No veterinary medicinal product on market unless marketing authorisation

BUT derogations

For Food producing -> substance should be in Annex I, II or III

8

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org

Art 10 CASCADE

If there is no authorised product available, veterinarians can in exceptional cases, in particular in order to avoid unacceptable suffering use:

1. Product authorised for other species or indication
2. Human product
3. Product authorised in other EU Member State
4. Extemporaneously made product

For food producing animals only substances included in annexes I, II or III of REG (EEC)2377/90 (MRL) !

WP for meat 28 days

9

Cascade

Is there an authorised product for this species and indication?

```

    graph TD
      Q1{Is there an authorised product for this species and indication?}
      Q1 -- NO --> Q2{Under exceptional circumstances and in particular to avoid unacceptable suffering you are allowed to use the Cascade. Is this the case?}
      Q1 -- YES --> A1[Use authorised product]
      Q2 -- YES --> Q3{Is there a suitable product authorised for another species/condition in your Member State?}
      Q2 -- NO --> Q4{Is there a human product authorised in your Member State or a VMD from another Member State?}
      Q3 -- YES --> A2[Use this authorised product]
      Q3 -- NO --> Q4
      Q4 -- YES --> A3[Use either one of these products]
      Q4 -- NO --> Q5{Is it possible to extemporaneously prepare a product?}
      Q5 -- YES --> A4[Prepare extemporaneously]
      Q5 -- NO --> A5[No treatment with M.P. is allowed]
  
```

Specific precautions for food-producing animals:

- Active substances have to appear in annex I, II or III of regulation 2377/90 and withdrawal periods have to be specified.
- Unless already indicated for the species concerned, withdrawal periods have to be at least:
 - 7 days for eggs
 - 7 days for milk
 - 28 days for meat
 - 300 days/age for fish meat
- The veterinarian has to keep records for 5 years at:
 - Date of administration
 - Details of the owner
 - Number of animals treated
 - Clinical product prescribed
 - Doses administered
 - Duration of treatment
 - Recommended withdrawal period

10

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org

Art 10 CASCADE

"...Member States **may** exceptionally, in particular in order to avoid causing unacceptable suffering to the animals concerned, **permit** ..."

↓

"Member States **shall take the necessary measures to ensure** that,....."

11

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org

HORSES

In principle, every horse is considered as a food producing animal

However, one can declare a horse as:


being not intended for slaughter

This has to be **recorded in the horse passport**

Irreversible!

12

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org



POSSESSING, DISPENSING AND DISTRIBUTION

13

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org



Supply of veterinary medicines

Art 66:

- Only by persons who are permitted
- Shall keep detailed records
- Spec paragraph medicines for food producing species

14

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org



POM/NON-POM

Art 67. General rule: all products for food producing animals must be prescribed by qualified person

MSs can make exemptions

Only within certain criteria

15

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org



Exemption Criteria
Directive 2006/130/EC

- Formulations requiring no particular skills or knowledge
- No (-in)direct risk for animals or person administering it
- No potential serious side effects when correctly used
- No history of frequent adverse reactions
- No special storage conditions
- No risk for consumer safety even when used incorrectly
- No risk for development of resistance to antimicrobials or anthelmintics

ALL CRITERIA HAVE TO BE SATISFIED !

16

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org



Record keeping farmers (art 69)

Owners/keepers shall provide proof of purchase, possession and administration of veterinary medicines products for 5 years

MS may require additional record keeping

17

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org



Vets providing cross-border services

- Vets can take with them and administer small quantities of medicines not exceeding daily requirements
- Certain conditions attached...

18

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org



Title VII: Pharmacovigilance (art 72-74)
Title VIII: Supervision and Sanctions (art 75-88)

19

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org



ADVERTISING (art 85)

Prohibit advertising to general public of

- Medicines under prescription
- Containing psychotropic drugs or narcotics

20

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org




EMEA & CVMP



21

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org




- decentralised body of EU
- headquarters in London
- protection and promotion of public and animal health, through the evaluation and supervision of medicines for human & vet use
- evaluation of applications for European marketing authorisation

22

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org



CVMP:

- Committee for Medicinal Products for Veterinary Use (CVMP)
- role:
 - * centralised procedure
 - * CVMP arbitrates in cases where is a disagreement between Mss
 - * sets MRL limits
 -

23

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org



CVMP structure

- * a chairman
- * 1 member (& alternate) nominated by each of the 27 EU Member States;
- * 1 member (& alternate) nominated by EEA-EFTA states Iceland and Norway
- * max 5 co-opted members, chosen among experts nominated by

24

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org



Title IX: Standing Committee (CVMP art 88-89)

Title X: General provisions

Title XI: Final measures

25


FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org



Regulation 2377/90
laying down maximum residue limits (MRL's)

26

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org



Classification

4 classes of substances
(Annexes 1, 3, 2 and 4 of Regulation 2377/90)

- **Annex I:** A maximum residue limit
 - *On the base of opinion of CVMP*
- **Annex II:** The absence of a maximum residue limit
 - *Not necessary for protection of human health*
- **Annex III:** A provisional maximum residue limit
 - *Incomplete data*
- **Annex IV:** A prohibition on the administration of a substance
 - *Where any use constitutes a hazard*

27

FVE Federation of Veterinarians of Europe
www.fve.org • info@fve.org




28