



Federation of  
Veterinarians of Europe

[www.fve.org](http://www.fve.org) • [info@fve.org](mailto:info@fve.org)



## **Workshop on Strengthening livestock health and Veterinary Services**

*Kiev, 2-3 November 2010*

**TAIEX**, AGR 42266



Federation of  
Veterinarians of Europe

www.fve.org • info@fve.org



# **Session III:**

## **Overview Veterinary Medicines Legislation in the EUROPEAN UNION**

Nancy De Briyne DVM  
FVE Dep Exec Director



Federation of  
Veterinarians of Europe

[www.fve.org](http://www.fve.org) • [info@fve.org](mailto:info@fve.org)



## **Federation of Veterinarians of Europe**

**44 veterinary organisations  
in 38 European countries**

**Through its members,  
FVE represents approximately  
200 000 veterinarians**





Federation of  
Veterinarians of Europe

[www.fve.org](http://www.fve.org) • [info@fve.org](mailto:info@fve.org)



founded in 1975

**FVE unites**

**the European veterinary profession** for  
the benefit of animal health, animal  
welfare and public health.



## **4 Sections: reflect the diversity of the veterinary profession:**

1. UEVP Veterinary Practitioners
2. UEVH Hygienists and Public Health Vets
3. EASVO State Veterinary Officers
4. EVERI Veterinarians in industry, research and education



Federation of  
Veterinarians of Europe

[www.fve.org](http://www.fve.org) • [info@fve.org](mailto:info@fve.org)



## **FVE**

wishes to be a platform for all members of the  
veterinary profession in Europe and to formulate their  
opinions in one corporate voice

**One Profession**  
**One Vision** **One Voice**



Federation of  
Veterinarians of Europe

[www.fve.org](http://www.fve.org) • [info@fve.org](mailto:info@fve.org)



**FVE**  
**strongly believes in the need**  
**for good cooperation between**  
**veterinarians in different positions**

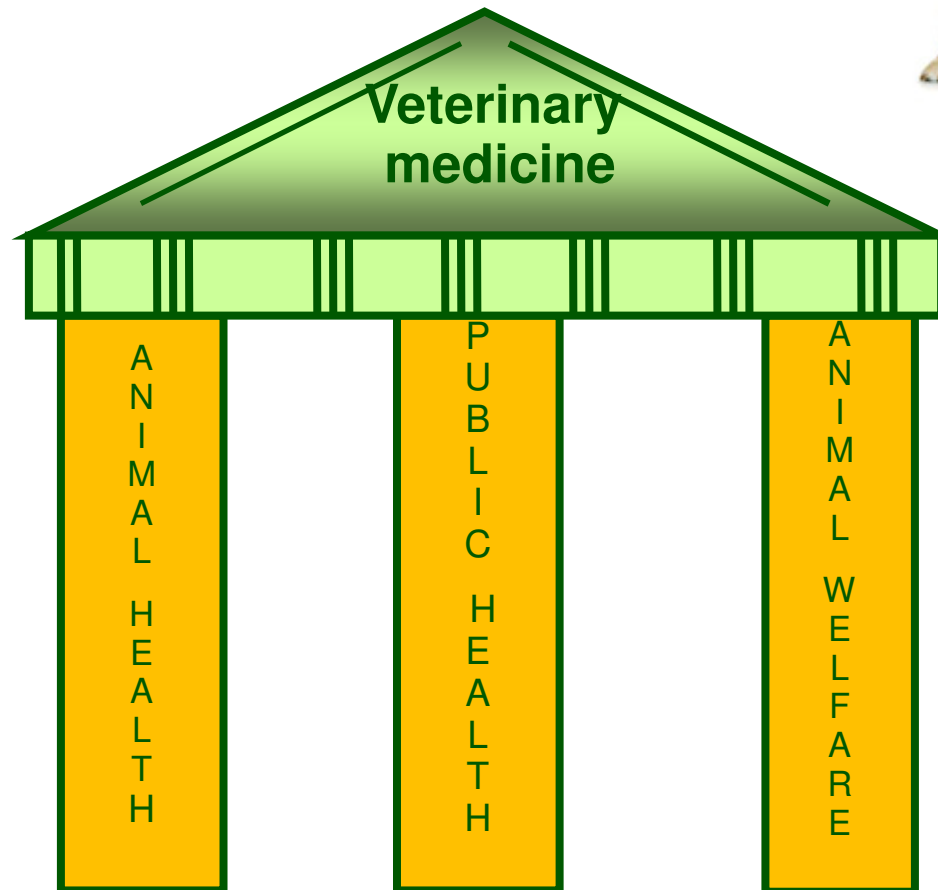
private and public  
practitioner, official veterinarians  
profession and science  
profession and academia  
profession and industry

**Synergy is our strength!**



Federation of  
Veterinarians of Europe

[www.fve.org](http://www.fve.org) • [info@fve.org](mailto:info@fve.org)



Research



Federation of  
Veterinarians of Europe

www.fve.org • info@fve.org



# European Medicines Legislation

**DIRECTIVE  
2001/82/EC  
(modified by Dir  
2004/28/EC)**





Federation of  
Veterinarians of Europe

www.fve.org • info@fve.org



# **VET MED DIRECTIVE**

## **Directive 2001/82/EC**

(revised by Dir 2004/28/EC)





## **Directive 2001/82/EC**

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



## DEFINITIONS & SCOPE (art 1-4)

- Veterinary Medicinal Product
- Veterinary Prescription
- Scope



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)



## MARKETING (Art 5-..)

General principle:

***No veterinary medicinal product on market unless marketing authorisation***

Marketing Authorisation: Granted per product following assessment of **quality, safety** and **efficacy**.



Federation of  
Veterinarians of Europe

www.fve.org • info@fve.org



*Centralised  
Procedure*



*Decentralised  
Procedure*



Federation of  
Veterinarians of Europe

[www.fve.org](http://www.fve.org) • [info@fve.org](mailto:info@fve.org)



## USE of VMP's

Principle: only allowed to use  
medicines authorised for a  
certain species

But derogations



## 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

WP for meat 28 days

# Cascade

Is there an authorised product for this species and indication?

NO

Under exceptional circumstances and in particular to avoid unacceptable suffering you are allowed to use the Cascade. Is this the case?

YES

Is there a suitable product authorized for another species/condition in your Member State?

NO

Is there a human product authorised in your Member State or a V.M.P. from another Member State?

NO

Is it possible to extemporaneously prepare a product?

YES

YES

YES

YES

NO

YES

Use authorised product

Use this authorised product

Use either one of these products

Prepare extemporaneously

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 2377/2003 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
  - 500 degree-days for fish meat
- The veterinarian has to keep records for 5 years of:
  - Date of examination
  - Details of the owner
  - Number of animals treated
  - Diagnosis
  - Medicinal product prescribed
  - Doses administered
  - Duration of treatment
  - Recommended withdrawal period



Federation of Veterinarians of Europe



Federation of  
Veterinarians of Europe

www.fve.org • info@fve.org



## HORSES ARE SPECIAL

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

**Special  
rules  
apply!**

However, one can declare a horse as:

**being not intended  
for slaughter**

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





Federation of  
Veterinarians of Europe

[www.fve.org](http://www.fve.org) • [info@fve.org](mailto:info@fve.org)



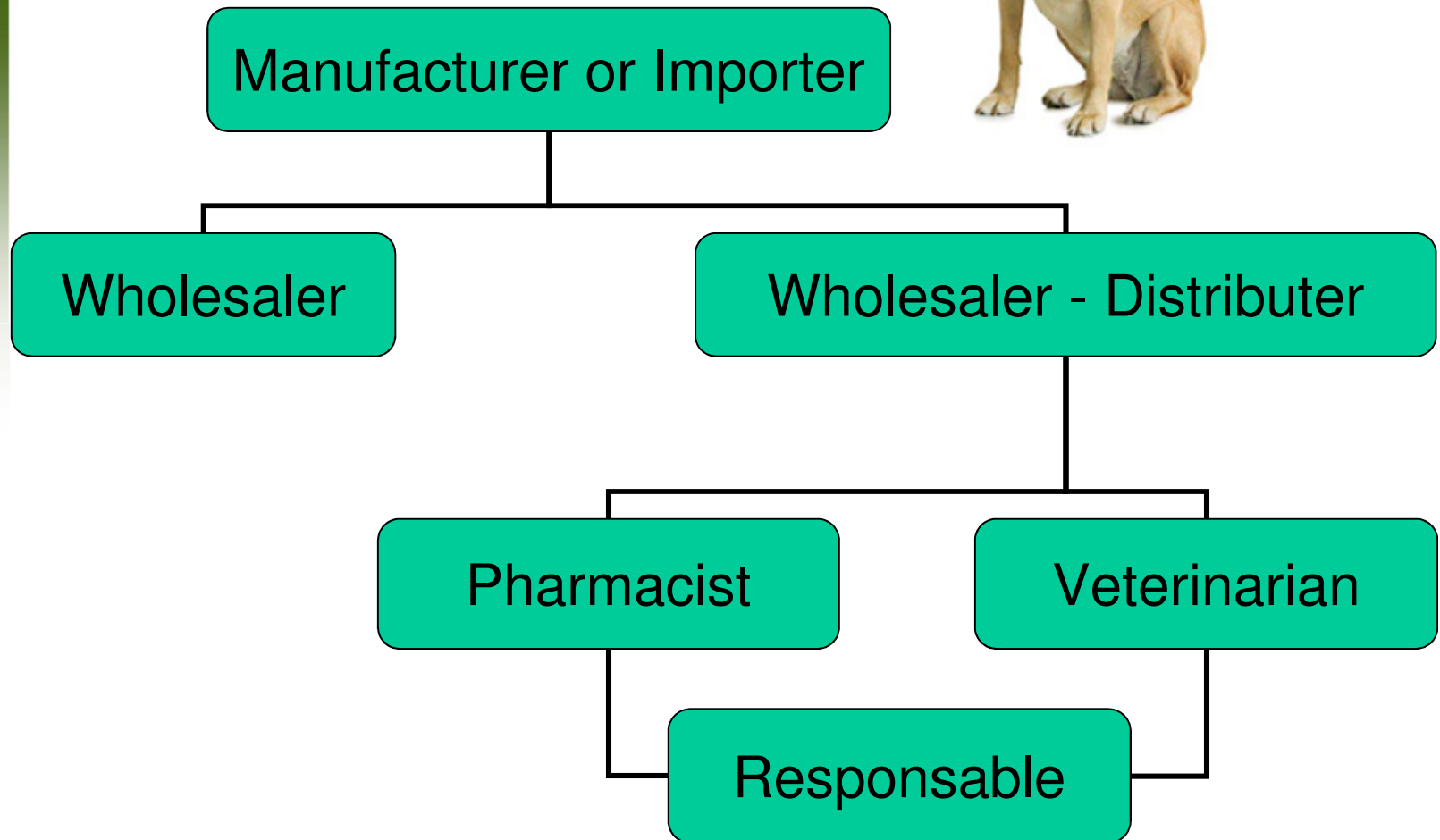
## **POSSESSING, DISPENSING AND DISTRIBUTION**



## **SUPPLY of VMP's**

Art 66:

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





Federation of  
Veterinarians of Europe

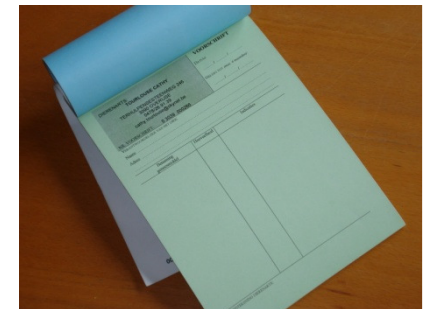
www.fve.org • info@fve.org



## Prescription Only Medicines (POM)/NON-POM

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

MSs can make exemptions – respecting certain criteria





## 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 !**

**All  
VMP's  
must be  
traceable!**

Association of  
Veterinarians of Europe  
www.fve.org • info@fve.org



## Record keeping

- Farmers shall keep for 5 years:
  - proof of purchase,
  - possession and
  - Administration
- All persons responsible of stock keeping must keep records e.g an in/out register
- All vets are responsible for the traceability of the dispensed VMP



## Vets providing cross-border services

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



Federation of  
Veterinarians of Europe

[www.fve.org](http://www.fve.org) • [info@fve.org](mailto:info@fve.org)



Title VII: Pharmacovigilance (art  
72-74)

Title VIII: Supervision and  
Sanctions (art 75-88)



## **ADVERTISING (art 85)**

Prohibit advertising to general public of

- Medicines under prescription
- Containing psychotropic drugs or narcotics



Federation of  
Veterinarians of Europe

[www.fve.org](http://www.fve.org) • [info@fve.org](mailto:info@fve.org)



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

Title X: General provisions

Title XI: Final measures



Federation of  
Veterinarians of Europe

[www.fve.org](http://www.fve.org) • [info@fve.org](mailto:info@fve.org)



## PHARMACOVIGILANCE

“not an option  
but an **obligation**“





## Pharmacovigilance

- **What** is monitored?
- **How** is it monitored?
- **Vets** and pharmacovigilance



Federation of  
Veterinarians of Europe

[www.fve.org](http://www.fve.org) • [info@fve.org](mailto:info@fve.org)



**What** is monitored?



## **What** is monitored?

Adverse reactions

Serious adverse reactions

Human adverse reactions



Federation of  
Veterinarians of Europe

[www.fve.org](http://www.fve.org) • [info@fve.org](mailto:info@fve.org)



**How** is it monitored?



Federation of  
Veterinarians of Europe

www.fve.org • info@fve.org



Products authorised  
central via EMEA

Products authorised  
de-centralised via  
national PV

EudraVigilance Veterinary



Latest News

## What is Eudravigilance Veterinary

Meetings/Training

EudraVigilance Veterinary is the European data-processing network and database management system for the exchange, processing and evaluation of Suspected Adverse Reaction Reports (SARs) related to veterinary medicinal products authorised in the European Economic Area (EEA), this is the European Union, Norway, Iceland and Liechtenstein.

Info To Public

Pharmacovigilance in general concerns the surveillance of veterinary medicinal products, with particular reference to adverse reactions in animals and human beings related to the use of veterinary medicinal products. Pharmacovigilance also comprises available information related to the lack of expected efficacy, off-label use, investigations of the validity of the withdrawal period and on potential environmental problems arising from the use of the product.

What is EYVET

- Components
- How To Report
- How To Register

EudraVigilance is a key component in supporting the Member States and the EMEA within its Scientific Committees in the co-ordination of the supervision, under practical conditions of use, of veterinary medicinal products which have been authorised within the EEA and the provision of advice on the measures to ensure the safe and effective use of these products, in particular by evaluating and making available through a pharmacovigilance database, information on adverse reactions to the veterinary medicinal products in question.

Legislation/Guidelines

## How to register with EudraVigilance Veterinary

Reference Documents

- Release Notes
- Standards
- Downloads
- Electronic Reporting in the Member States

- ◆ Access Online Registration forms
- ◆ Download a pdf version of "How to Register with EudraVigilance"

The registration process is necessary to identify the partners of the EMEA in the EEA for the secure electronic transmission of ADRs. Only registered partners are permitted to exchange safety or acknowledgement messages through the EudraVigilance Veterinary Gateway and Database Management System (DBMS).

Tutorials

Pharmaceutical Companies and national Competent Authorities can register on this website for the purpose of the secure electronic transmission of ADRs and to become part of the EudraVigilance Veterinary user community.

Questions and Answers

- General
- Info to MAHs
- Technical Document

It is recommended to download and to read the user manual on the registration process.

### Test and production environments

EudraVigilance Veterinary has two different environments:

- ◆ The **test environment** is for the testing of electronic transmission of ADRs and to enable users to get used to the system;
- ◆ The **production environment** is for the regular electronic transmission of ADRs.

Help Desk

Each organisation must provide two different Organisation IDs: one for the EudraVigilance Veterinary Test Environment and one for the EudraVigilance Veterinary Production Environment. The Organisation IDs must be different. The organisation ID must comprise between 3 and 10 characters, and should consist of upper case letters (A to Z) and/or numbers (0 to 9), not using spaces or special characters. For easy recognition of the Organisation and the Member State where it is located, it is further recommended to start the Organisation ID with the two-letter country code according to ISO.

Useful Links

### Documents required for registration

To successfully complete the registration process you need to post several documents to the EMEA. Among those are the printed forms obtained



Federation of  
Veterinarians of Europe

[www.fve.org](http://www.fve.org) • [info@fve.org](mailto:info@fve.org)



# Vets and pharmacovigilance?



Veterinarians are more motivated to report adverse effects, when they see an added value:

- when they encounter something new
- when it is considered a serious case
- when it does not cause too much extra work
  - preferably on-line reporting
- when they get feedback on the report
- when the owner of the animal complains



# EMEA & CVMP





Federation of  
Veterinarians of Europe

www.fve.org • info@fve.org



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## EMEA:

- 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



## 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



## Conclusions 1/2:

- VMP's are highly regulated



All vet meds have to be authorised



Only medicines licensed in the country for the species can be used



Strict rules apply to ensure traceability



## Conclusions 2/2:

- Although much EU harmonisation no real free market for VMP's
- Balancing between safety/quality and availability
- Pharmacovigilance is an obligation



Federation of  
Veterinarians of Europe

www.fve.org • info@fve.org



## The story never ends....

- Revision legislation
- Antibiotic resistance
- Prudent use

***... and FVE will continue to promote the central role vets play in the food chain, and in the supply and administration of VMP's***



Federation of Veterinarians of Europe

www.fve.org • info@fve.org



For more information:

\* FVE

[www.fve.org](http://www.fve.org)

+32 2 533 7020

[info@fve.org](mailto:info@fve.org)

