Workshop on Strengthening livestock health and Veterinary Services

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TAIEX, AGR 42266
Session III:

Overview Veterinary Medicines Legislation in the

EUROPEAN UNION

Nancy De Briyne DVM
FVE Dep Exec Director
Federation of Veterinarians of Europe

44 veterinary organisations in 38 European countries

Through its members, FVE represents approximately 200,000 veterinarians
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
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
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!
Veterinary medicine

Research

Animal Health

Public Health

Animal Welfare
European Medicines Legislation

DIRECTIVE 2001/82/EC
(modified by Dir 2004/28/EC)
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.
Centralised Procedure

Decentralised Procedure

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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 authorised for another species/condition in your Member State?
    - NO
      - Use authorised product
    - YES
      - 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
              - Prepare extemporaneously
            - NO
              - No treatment with M.P. is allowed
        - YES
          - Use this authorised product

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
  - 26 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
HORSES ARE SPECIAL

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

Title X: General provisions

Title XI: Final measures
PHARMACOVIGILANCE

“not an option but an obligation“
Pharmacovigilance

- **What** is monitored?

- **How** is it monitored?

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

Adverse reactions

Serious adverse reactions

Human adverse reactions
How is it monitored?
Products authorised central via EMEA

Products authorised de-centralised via national PV

EudraVigilance Veterinary
What is EudraVigilance Veterinary

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.

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.

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.

How to register with EudraVigilance Veterinary

- 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).

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.

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.

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...
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:
- 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

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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
For more information:

* FVE
www.fve.org
+32 2 533 7020
info@fve.org