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Candidate Countries preparing for implementing the VMP Legislation

The practitioner's point of view

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Board Member VDV

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VDV

- Flemish Veterinary Association
- Non profit organisation
- Defence of veterinary interests
- Walloon sister association UPV
- Member of FVE
- Involved in implementation of VMP legislation in Belgium

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Objectives EU and VMP legislation

- Freedom of Movement
- Biggest and most powerful economical area
- In respect of:
 - Animal Health
 - Animal Welfare
 - Public Health



Scoop Legislation

- One single text: Directive
- Marketing
- Manufacture and Imports
- Labelling and Packaging Insert
- Possession, Distribution and Dispensing
- Pharmacovigilance
- Supervision and Sanctions
- Standing Committee

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Possession, distribution, dispensing

- Universal and transparent
- Abolishment of contradictory national legislation
- Tracability VMP in FPA and CA!



Possession, distribution, dispensing

And also take into account:

- Regional differences (economically, veterinary practice,...)
- CA versus FPA
- Large scale food production versus small scale production

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Threat or challenge?

- Supranational legislation
- European interference
- Adaptation
- Administrative burge
- Need for informatisation
- Transparency: medication use, financial
- Control measures

Mentality change



Threat or challenge?

- Vet
 - Broad education
 - Key person in supervision of VMP in animals
- Availability of VMP: Cascade – MUMS
- Centralised pharmacovigilance
- Responsibility circumscribed
- Specific accents possible



Legal Framework

European VMP legislation

- Directive 2001/82/EC
- Directive 2004/28/EC

Has been embraced in Belgium 😊

Vet representants versus vet profession...

- Stronger position eg towards pharmacists
- Confirmation vet as VMP dispenser
- Circumscribed responsibility

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BUT...

- Why is administrative burge necessary for CA?
- Is administrative simplification possible for CA?
- What about mixed practices?



BUT...

- Can we impose administrative burge to farmers?
- Can we impose less stringent rules to farmers?
- Do we still reach one of the main objectives: safe food?

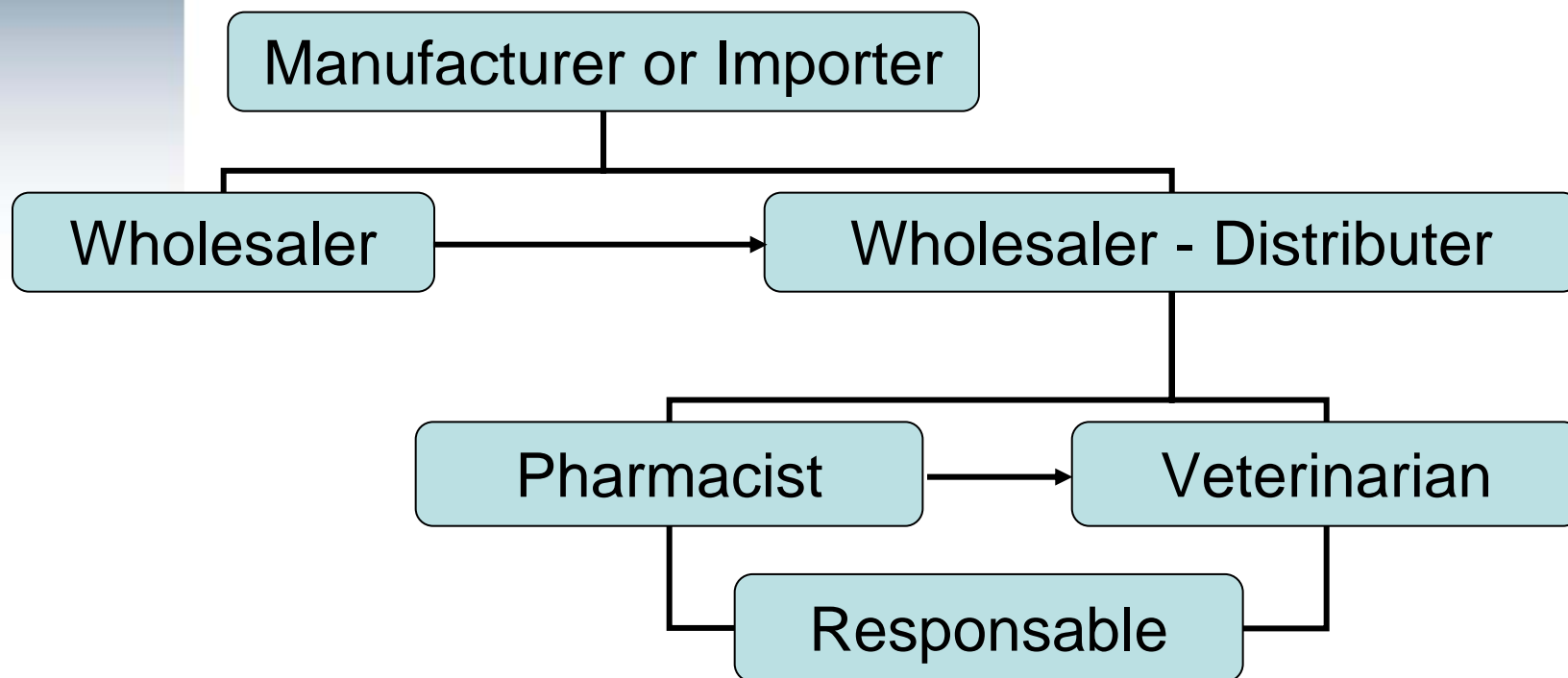


Implementation

- Medicine distribution
- Medicine stock
- Ordering medication
- Registers IN and OUT
- Administration and Supply Doc's
- Prescription – POM and non POM
- MUMS and Cascade



VMP Distribution





Medicine stock

- Holder = vet (natural person)
- One per vet – no transfers in between stocks
- Identification number
- Association:
 - One responsible for ordering, list users, contact authorities etc
 - Individual responsibility regarding supply and administration
- Only supply from wholesaler

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Entrance VMP

- Order Form (double)
- Unique number
- Signed by vet and supplier: in register
- Updated daily
- Kept for 10 years



Register IN

- Date
 - Identity medication
 - Batch number
 - Quantity received
 - Name and address supplier
-
- Updated daily
 - Delivrance notice of wholesaler
 - Electronically possible



Register OUT

- Date
 - Identification medicine
 - Batchnumber
 - Quantity
 - Name and address destinator
 - Species
-
- Per individual vet
 - Daily
 - Electronically possible

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Stock Check

- Yearly
- Comparison register IN and OUT
- Record for differences
- Kept for 5 years

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Administration and Supply Doc's

- ASD
- Different rules CA versus FPA



ASD FPA

- For every supply of med's
- For administration of med's in defined period before slaughter
- Always for
 - VMP with hormonal, antihormonal, beta adrenergic or production stimulating activity
 - Official diseases (exc if official doc)

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ASD CA

- Only for official diseases
- Exception: official doc



ASD

- Disease
- Identity, batchnumber, quantity medication
- Instructions for use, withdrawal period
- Signature vet
- Countersigned by responsible

Can be register OUT

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Labelling supplied VMP

Always on immediate packaging

With ASD

- Name vet
- Number ASD

Without ASD

- Name vet
- ID depot
- Date supply



Prescription

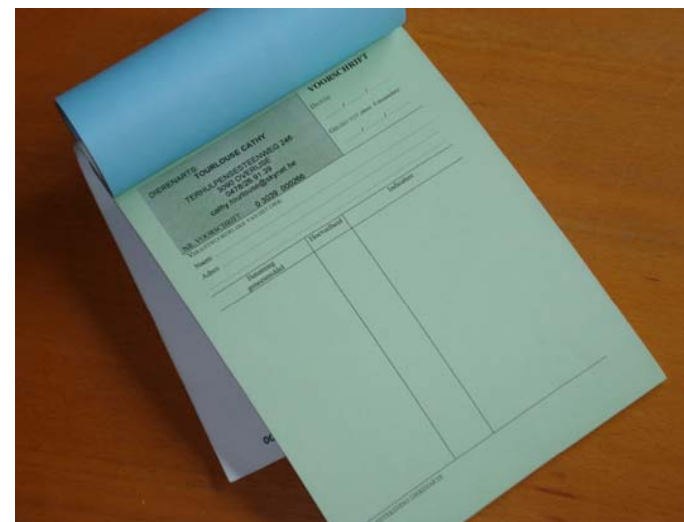
- Is more than 'instructions for use'
- Premade doc that permits farmer to collect VMP's at pharmacist
 - Details stock holder
 - Individual number
- 2 or 3 copies
- Limited validity



Prescription

Fill in spaces

- Date
- Name and address responsible
- ID animal or group
- Name and quantity VMP
- Disease
- Instructions for use, withdrawal period
- Validity period prescription
- Signature vet
- Countersigned by responsible





POM

- Products with official restrictions on supply or use
 - Narcotic and psychotropic substances
 - Restrictions resulting from Community law
- VMP for FPA (exceptions possible)
- Precautions to avoid unnecessary risk to target species, person administering, environment
- Precise prior diagnosis needed or if use can impede or interfere with subsequent diagnosis or therapy
- Officinal formula for FPA
- New products with active substance on the market for less than 5 years



Non POM

- Formulations requiring no particular knowledge or skills for use
- No risk for target species, administrator, environment
- No warnings for potential serious side effects with correct use
- No frequent serious adverse reaction



Non POM

- No contraindications related to other VMP commonly used without prescription
- No special storage conditions
- No risk for consumer safety regarding residues, even if used incorrectly
- No risk for development of resistance (bacterial – anthelmintic), even if used incorrectly



Cascade

- If no authorised VMP for disease
- To avoid unacceptable suffering
- By means of exception
- Under responsibility of veterinarian



Cascade CA

Authorised VMP for other species or for other indication in same species



Human MP in MS or VMP in other MS



Ex tempore preparation



Cascade FPA

Same as CA but:

- Active substances have to appear in annex I, II or III of Regulation 2377/90 and withdrawal periods have to be specified
- Unless indicated for species concerned: minimal withdrawal period
- Records for 5 years



Cascade Horses

Non foodproducing horse: cascade for CA

Food producing horse: cascade for FPA
(withdrawel period at least 28 days)

No solution in FPA cascade: positive list
(withdrawal period at least 6 months)

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MUMS

- Minor Species Minor Uses
- Simplified registration procedure
- Probably no application in Belgium



Obligations farmer

- All VMP must be tracable
 - Register of prescriptions and ASD
 - Chronological, individually numbered
 - In immediate packaging

- If no guidance contract
 - VMP for no longer than 5 days to finalise started treatment by vet



Obligations farmer

- If guidance contract
 - Register per species
 - Administered medication in pre slaughter period
 - Reference to number prescription or ASD
 - Outside pre slaughter period: post certification if VMP used and suspicion of residu's

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Conclusions

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Conclusions

- Vets don't like changements
- Pro-active work is not always rewarding
- Acceptation takes time
- Clarify the European context
- Emphasize the advantages
- Computers make life easier
- Tracability can't end at the entrance of the stable

THANK YOU