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New Regulations on 1. Veterinary Medicinal Products & 2. Medicated Feed

CDG on poultry and eggs - 16 July 2019

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Representing over 300 companies both originators and generics - 135 of which are small and medium sized enterprises (SMEs)

90% of European sales

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The pathway to new Veterinary medicines

Developing new medicines and vaccines requires extensive research and testing

2 years | 3 years | 2–3 years (seasons) | 1–2 years | = 8–10 years

DISCOVERY

Hypothesis development and early research

PRE-CLINICAL LAB DEVELOPMENT

Early testing in labs

Safety and quality including environmental safety

CLINICAL FIELD TRIALS

Testing safety and efficacy in animal patients

REGISTRATION

Product approval

Evaluation and assessment by regulatory authority

MANUFACTURE AND DELIVERY

Getting approved products to people or veterinarians to enable them to care for their animals

Aim of the new legislation

- Increase availability of veterinary medicinal products
- Reduce administrative burden
- Stimulate competitiveness and innovation
- Improve the functioning of the internal market
- Address the public health risk of AMR

VMP legislation covers:

1. Scope and definitions
2. Data requirements to obtain a marketing authorisation
3. Regulatory procedures to obtain a marketing authorisation
4. Keeping up-to-date - post-authorisation regulatory work
5. Pharmacovigilance - in market safety surveillance
6. Manufacturing controls
7. Use, distribution, retail
8. Inspections, controls and penalties

What is new… and what matters to you

1. Access to vet meds
2. New and innovative medicines
3. Prescription and use
4. Antibiotics
5. Labelling and other end user concerns

1. ACCESS

Regulation = one set of rules for all Member States without deviation. Some subsidiarity allowed.

Access to medicines:

- Changes to procedures mean greater access across the Union via a centralised procedure
- BUT: longer procedures, less transparency
- Harmonisation of summaries of product characteristics will also enable more expedient marketing of products in more countries. Gradual approach via annual prioritised list of products

2. INNOVATION

- Stimulus for minor species
- No stimulus for line extensions for major species
- Some stimulus for new antibiotics
- Some stimulus for some innovation on existing products
- Reduced requirements for exceptional circumstances, limited markets
- Improved route to market for novel therapies

3. PRESCRIPTION

Major changes for veterinarians

- **Prescriptions and use**
  - common format, electronic, valid throughout EU; quantity prescribed limited to treatment needs; restrictions for antibiotics and use of autologous vaccines
  - Prophylaxis – only in exceptional cases; metaphylaxis – only if high risk of disease
- **Prescription cascade**
  - simplified, but always veterinary product before human medicinal product; restrictions for antibiotics, including no antimicrobials reserved for human use
- **Mandatory collection of use data for antimicrobials**
  - First for livestock
  - Later will be extended to other species and other medicines
- **Implementing measure on rules for oral medication**
  - via drinking water or top dressing. EC to provide guidelines

4. ANTIBIOTICS

- Ban on preventive use except in exceptional circumstances
- Restrictions on metaphylactic use
- Criteria/List of antimicrobials reserved for human use
- Re-stated ban on use of antibiotics for growth promotion
- Possibility to restrict use in the cascade
- Member States may further restrict use
- Restrictions placed on third country operators to import products derived from animals treated with reserved antibiotics
- Mandatory collection of sales and use data

5. OTHER END USER / SINGLE MARKET IMPROVEMENTS

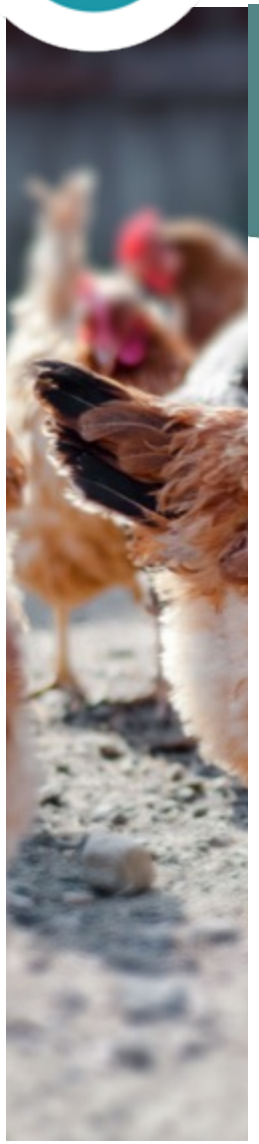
- **Distribution & retail**
  - Wholesale/distribution licence valid throughout the Union
    - *Implementing Acts on 'Good Distribution Practice*
  - Vet prescriptions valid throughout the Union
  - On-line sales permitted (only for non-prescription products)
  - Parallel trade better defined

- **Packaging and labelling**
  - ➢ reduced text, no additional text allowed, pictograms and standard abbreviations allowed

What's next?

- Impact? Depends how the legislation is implemented
- 25 implementing measures on the details
  - 17 Implementing Acts
  - 8 Delegated Acts
  - 15 to be adopted in next 3 years (January 2022)
- ALSO: major new systems need to be put in place
  - **Pharmacovigilance**
  - A completely new chapter (harmonisation of product summaries)
  - **IT infrastructure** – databases, electronic submission, single e-submission portal, data management systems (SPOR)
  - **Major impact! - b**ut positive or negative on admin burden depends on how it is implemented

New Regulation on Medicated Feed



The 3Cs of Medicated Feed

Control

- ✓ Always subject to prescription from a veterinary surgeon
- ✓ Manufactured using Hazard Analysis at Critical Control Point (HACCP) systems
- ✓ Full traceability at all times
- ✓ Excellent control of withdrawal time for optimal consumer safety
- ✓ Quantities of feed matches prescription (no waste)
- ✓ Minimal risk of incorrect dosing due to human error

Compliance

- ✓ Ensures full compliance with prescription
- ✓ Efficient system - farmer or caretaker are available for other tasks
- ✓ Ease and safety of administration to individual or groups of animals
- ✓ Well-adapted for some diseases like digestive conditions in food animals and parasitic or chronic conditions in companion animals

Care

- ✓ Most practical option to treat certain animals (e.g. farmed fish)
- ✓ No stress for animals who do not need to be handled
- ✓ Less stress and risk of injury for the animal owner and veterinarian when administering the medication to the animal(s)

2019/4 now adequately regulates Medicated Feed

- EFSA mandated to set cross-contamination limits for antimicrobial carry-over between batches of medicated feed before 2022.
- Drinking water/oral powders (top dressing): EC aims to have practice regulated by end 2021
- Realistic and practical tolerances
- Medicated Feed for pets: now a viable option
- Anticipated production allowed

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Any questions?

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Thank you!